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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

MAYO CLINIC; and LIFEPOINT CORPORATE SERVICES, GENERAL PARTNERSHIP,

Plaintiffs,

v.

CELGENE CORPORATION; BRISTOL-MYERS SQUIBB COMPANY; NATCO PHARMA LIMITED; TEVA PHARMACEUTICALS USA, INC.; and DR. REDDY'S LABORATORIES, INC.,

Defendants.

Case No.: 3:23-cv-5144

DEMAND FOR JURY TRIAL

COMPLAINT FOR DAMAGES AND INJUNCTIVE RELIEF

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COMPLAINT

Plaintiffs Mayo Clinic and LifePoint Corporate Services, General Partnership (collectively, "Plaintiffs"), by and through their attorneys, bring this Complaint against Defendants Celgene Corporation ("Celgene"), Bristol-Myers Squibb Company ("BMS"), Natco Pharma Limited ("Natco"), Teva Pharmaceuticals USA, Inc. ("Teva"), and Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's), on personal knowledge as to each Plaintiff's own activities, on information and belief as to the activities of others, on information made public, and on the related consolidated actions already pending before Honorable Esther Salas in the United States District Court for the District of New Jersey, captioned *In re Revlimid & Thalomid Purchaser Antitrust Litigation*, 19-cv-7532 (hereinafter, "Consolidated Actions"). Defendants Celgene and BMS, the sole U.S. manufacturer of Revlimid from 2005 through 2022, through anticompetitive tactics and anticompetitive agreements with generic manufacturers, including Defendants Natco, Teva, and Dr. Reddy's, insulated, prevented, and delayed generic competition for Revlimid, which caused Plaintiffs to pay more than they should have for brand and generic Revlimid in contravention of federal and state laws.

I. SUMMARY OF THE CASE

1. The United States patent system is designed to foster innovation by securing market exclusivity for inventors "for limited times." U.S. Const. Art. I, § 8. In the pharmaceuticals realm, a patent is designed to reward pharmaceutical companies for developing new drugs and to help compensate them for the research, development, and regulatory costs associated with such development.

2. Defendants Celgene and BMS were able to take full advantage of this exclusivity despite the fact that their "blockbuster" cancer drug Revlimid® was far from innovative—the Active Pharmaceutical Ingredient ("API") in Revlimid—lenalidomide—is an analogue of thalidomide, a drug that dates back to the 1950s and 1960s. Defendant Celgene also spent

comparatively little on researching and developing Revlimid. It was studies funded by the National Institutes of Health ("NIH") at Boston Children's Hospital and Dana Farber Cancer Institute that discovered thalidomide and its analogue EM-12 were effective at treating multiple myeloma, a type of blood cancer.[1] And yet, Celgene was able to obtain a patent from the United States Patent and Trademark Office ("USPTO") for its thalidomide-derived drugs, including Revlimid, U.S. Patent No. 5,635,517 (filed July 24, 1996) on June 3, 1997 (the "'517 Patent").

3. Because a patent guarantees market exclusivity in the United States—a legal monopoly—until the patent expires, once a patent-protected drug is permitted to enter the pharmaceutical marketplace, the pharmaceutical company can—and often does—charge whatever price it wants for the branded drug because there are no market forces preventing it from doing so. The '517 Patent expired on October 4, 2019 and so, too, should have Celgene's Revlimid monopoly, but due to the anticompetitive actions of Celgene, and later, BMS, they have managed to maintain a monopoly on Revlimid until at least January 2026—more than six years after expiration of the Revlimid patent.

4. After launching Revlimid in 2005, Defendant Celgene raised the price of the blockbuster cancer drug *22 times* (going from $215 per pill in 2005 to $719 per pill in 2018).[2] After Defendant BMS acquired Defendant Celgene in or about November 2019, the price for Revlimid escalated to an astounding $763 per pill.[3] As of late 2020, a one-month supply of Revlimid cost as much as $16,023, more than *triple* its price in 2005 ($4,515).[4] Despite generic versions of Revlimid entering the market in 2022, the cost of branded Revlimid has only

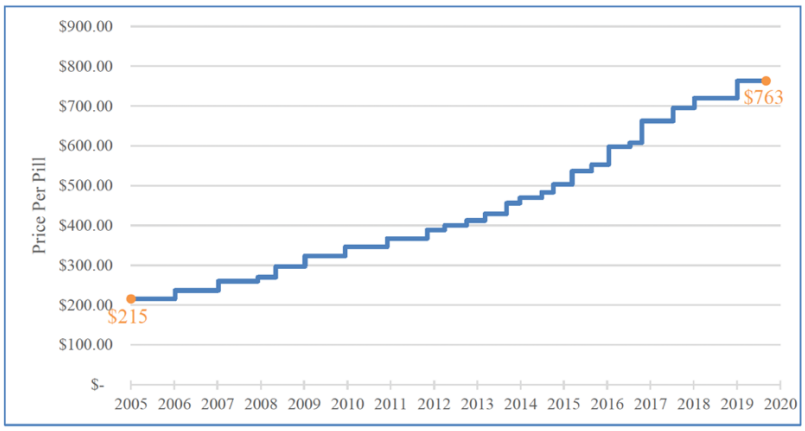
[1] *See* U.S. House Comm. on Oversight and Reform *Drug Pricing Investigation: Celgene and Bristol-Myers Squibb—Revlimid*, at 25-28 (Sept. 30, 2020), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/Celgene%20BMS%20Staff%20Report%2009-30-2020.pdf ("2020 Revlimid Report").

[2] *Id.* at 1.

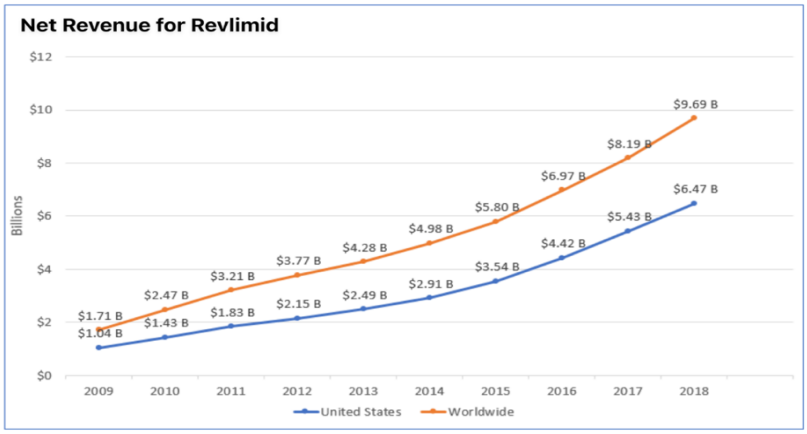
[3] *Id.*

[4] *Id.*

continued to skyrocket with a one-month supply costing as much as $24,576.29 in 2023,[5] a more than *five-fold* increase of its original price.



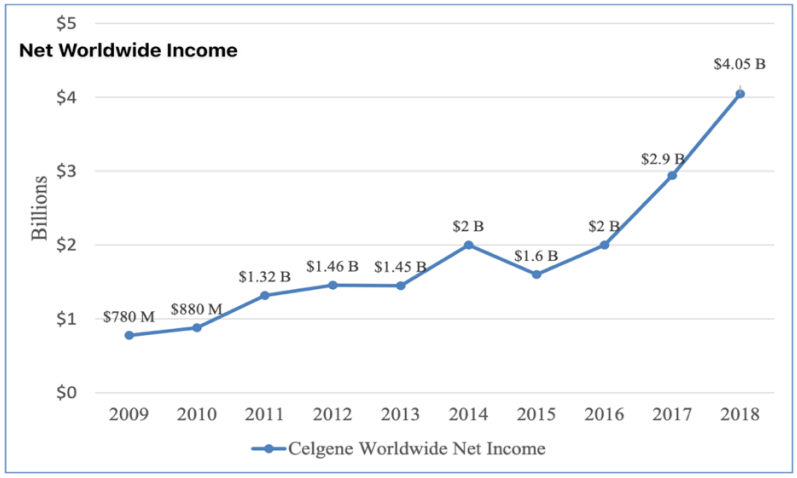
5. Defendants Celgene and BMS routinely ratcheted up the price of Revlimid for no reason other than to line the pocketbooks of Defendants Celgene and BMS, their executives, and their stockholders. As Celgene's former Senior Vice President of Sales and Marketing stated under oath, Celgene's executives could raise the price of Revlimid "any time they wanted" with impunity.[6] Celgene's net revenue for Revlimid sales in the United States increased from $1 billion in 2009 to nearly $6.5 billion by 2018 and its annual profits increased over the same period of time from $780 million to $4 billion.[7]



[5] *Revlimid Prices, Coupons and Patient Assistance Programs*, Drugs.com, https://www.drugs.com/price-guide/revlimid#:~:text=Revlimid%20(lenalidomide)%20is%20a%20member,on%20the%20pharmacy%20you%20visit (last visited Sept. 24, 2023).

[6] *Id.* at 4.

[7] *Id.* at i.



6. Meanwhile, Celgene's (and later, BMS's) executives earned millions in additional bonuses because of Revlimid price increases.[8] Revlimid's massive revenue was publicly acknowledged by BMS as a key asset of its acquisition of Celgene in 2019.[9]

7. Pharmaceutical companies' ability to price-gouge for branded drugs, however, if not limited by the bounds of common decency, *should* be limited by the expiration of the period of patent exclusivity. Once a patent nears its expiration date, generic pharmaceutical manufactures can begin the process of seeking approval from the United States Food and Drug Administration ("FDA") to manufacture generic versions of that branded drug to introduce into the marketplace once the branded drug's patent exclusivity expires.

8. Generally, the introduction of generic drugs into the marketplace significantly drives down the cost of pharmaceuticals for purchasers like Plaintiffs. The FDA estimates that the price of a branded drug drops by nearly 40% when a *single* generic competitor enters the market, by 54% when two generic competitors enter the market, and by more than 95% when six or more competitors enter the market.[10]

[8] *Id.* at 8.

[9] *Id.* at 2 (citing the 2019 Joint Proxy Statement filed by BMS and Celgene on February 22, 2019).

[10] *Id.* at 17-18 (citing U.S. Food & Drug Admin., *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* (Dec. 2019)).

9. These cost-savings, however, come at the expense of the branded drug manufacturer's profits. As Defendants Celgene and BMS recognized in their joint proxy statement during their 2019 merger, any "expiration or loss of patent protection with respect to REVLIMID® that occurs sooner than anticipated would be harmful to the combined company and could have a material adverse effect on its business, financial condition or results of operations."[11] For a blockbuster drug like Revlimid, *billions of dollars* are at stake and there is a significant financial advantage to abuse both the United States patent system and the FDA's regulatory approval process to delay and block generic entry into the market for as long as possible.

10. That is precisely what occurred here—Defendants Celgene and BMS engineered an anticompetitive scheme—later joined by Defendants Natco, Teva, Dr. Reddy's, and others—to thwart generic competition for Revlimid such that Defendants Celgene and BMS would not lose their pharmaceutical cash cow in October 2019, when the '517 Patent was set to expire. This anticompetitive scheme involved, at a minimum:

> (1) manipulating the FDA's Risk Evaluation and Mitigation Strategy ("REMS") drug safety program to refuse to sell lenalidomide—the API in Revlimid—to would-be generic competitors such that they could not timely develop generic equivalents to Revlimid;
>
> (2) preventing pharmaceutical ingredient suppliers from supplying Revlimid's API to would-be generic competitors such that they could not timely develop generic equivalents to Revlimid;
>
> (3) fraudulently seeking and obtaining at least 52 additional patents from the USPTO in an effort to retain monopoly power;
>
> (4) filing baseless regulatory petitions with the FDA to thwart and stymie regulatory approval of generic equivalents to Revlimid;
>
> (5) commencing serial (and baseless) patent infringement lawsuits against would-be generic competitors; and

[11] *2019 Joint Proxy Statement*, Bristol-Myers Squibb Co. and Celgene Corp., 48 (Feb. 22, 2019), https://www.sec.gov/Archives/edgar/data/816284/000114036119003696/ s002620x7_ defm14a.htm.

(6) conspiring with would-be generic competitors, including Defendants Natco, Teva, and Dr. Reddy's to resolve those serial (and baseless) patent infringement lawsuits by entering into anticompetitive "reverse payment agreements."

11. Despite the dilatory and abusive tactics by Defendants Celgene and BMS, multiple generic manufacturers were eventually able to obtain approval of an Abbreviated New Drug Application ("ANDA") for a generic version of Revlimid in spite of Celgene's and BMS's best efforts. Threatened with "true" market competition, Defendants Celgene and BMS combined and conspired with Defendants Natco, Teva, and later, Dr. Reddy's, by agreeing to resolve Celgene's and BMS's sham patent litigation against them through the execution of reverse payment or so-called "pay for delay" settlement agreements.

12. Natco, and its marketing partner Teva, agreed not to launch a generic version of Revlimid in the 5, 10, 15, and 25 mg strengths until March 2022 (and to further refrain from fully supplying the market with generic Revlimid until January 2026) in exchange for a limited, 7% share of the generic Revlimid market in those strengths beginning in March 2022, which would gradually increase through January 2026. Dr. Reddy's, in a separate reverse payment agreement, agreed not to launch a generic version of Revlimid in the 2.5 or 20 mg strengths until September 2022 (and to further refrain from fully supplying the market with generic Revlimid until January 2026) in exchange for a limited, 7% share of the generic Revlimid market in those strengths beginning in September 2022, which would gradually increase through January 2026.

13. The "reverse payment" to Natco/Teva and Dr. Reddy's included: (1) a volume-limited, royalty-free license guaranteeing them a limited share of the Revlimid market at prices close to the price of branded Revlimid (worth hundreds of millions of dollars to Natco/Teva and Dr. Reddy's); (2) most-favored entry plus clauses ("MFEP clauses") that both deterred later-filing generic manufacturers from challenging Celgene's patents and competing on equal terms with Natco/Teva and Dr. Reddy's; and on information and belief, (3) access to Celgene's FDA-approved REMS program for Revlimid. This ended up transferring value from Celgene and BMS to Natco/Teva and Dr. Reddy's in an amount that *far* exceeded the costs of litigating a patent infringement suit.

14. This payment was worthwhile to Celgene and BMS because it meant that the underlying patents on which it based its claim to market exclusivity for Revlimid would not be invalidated, as they surely would have been. After all, sharing a cash cow is better than not having the cow at all.

15. Pursuant to their agreements with Celgene and BMS, Teva launched Natco's approved generic lenalidomide in the 5, 10, 15, and 25 mg strengths in March 2022, but limited its sales to only 7% of that Revlimid sub-market, as opposed to the more than 90% share that a bioequivalent (or "AB-rated") generic normally would be expected to achieve. Similarly, Dr. Reddy's launched generic lenalidomide in the 2.5 and 20 mg strengths in September 2022, but limited its sales to only 7% of that Revlimid sub-market, as opposed to the more than 90% share that a bioequivalent (or "AB-rated") generic normally would be expected to achieve.

16. As a result of these agreements, Plaintiffs were deprived of any generic version of Revlimid from at least October 2019 through March 2022; have been forced to pay artificially high prices and face limited supplies of generic Revlimid beginning in March 2022; and will be deprived of the normal and expected results of generic competition in the Revlimid market until at least January 2026, when Defendants' reverse payment agreements expire.

17. Unfortunately, the anticompetitive effects of Defendants' conduct may be felt by Plaintiffs well beyond January 2026, given that Defendants Celgene and BMS have now effectuated a series of these reverse payment settlement agreements—with similar output-restriction, market-allocation, and MFEP terms—to resolve sham patent litigation with numerous other generic manufacturers. These settlements will continue to ensure supracompetitive generic prices for Revlimid for years to come at the expense of Plaintiffs.

18. Due to the above-described actions, Defendants have successfully delayed entry of generic lenalidomide into the United States market, restricted the supply of generic lenalidomide into the market, and artificially maintained the price of both Revlimid and generic lenalidomide at supracompetitive levels in violation of the Sherman Act, state antitrust laws, state consumer protection laws, and state common law until at least January 31, 2026.

19. These illegal and anticompetitive actions have caused Plaintiffs to pay overcharges on their purchases of Revlimid from Defendants Celgene and BMS and generic lenalidomide from Defendants Natco/Teva and Dr. Reddy's, as well as other generic manufacturers and will continue to cause these overcharges until at least January 31, 2026. Plaintiffs bring this action to recover damages for the overcharges they have already paid and to obtain equitable relief to stop the ongoing harm caused by Defendants' anticompetitive conduct.

II. JURISDICTION, VENUE, AND DIVISIONAL ASSIGNMENT

20. Plaintiffs bring this action under sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26, to obtain equitable and injunctive relief and damages for violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2. This Court has jurisdiction under 28 U.S.C. § 1331 for claims that arise under federal law and under 28 U.S.C. § 1337 for federal antitrust claims in particular.

21. Plaintiffs also assert claims for damages, to seek restitution, and to secure other relief under state antitrust, unfair competition, consumer protection, and unjust enrichment laws. The Court additionally has jurisdiction over these state law claims under 28 U.S.C. § 1367 because those claims are so related to the federal law claims that they form part of the same case or controversy.

22. Venue is proper in this District pursuant to 15 U.S.C. §§ 15 and 22 and 28 U.S.C. § 1391 because during the time period relevant to this action, Defendants transacted business throughout the United States, including in this District; Defendants resided, transacted business, were found, and/or had agents within this District, and a portion of the affected interstate trade and commerce discussed herein was carried out in this District.

23. Divisional assignment is proper in San Francisco/Oakland because during the time period relevant to this action, Defendants transacted business throughout the United States, including in San Francisco and Oakland; Defendants resided, transacted business, were found, and/or had agents within San Francisco and Oakland, and a portion of the affected interstate trade and commerce discussed herein was carried out in San Francisco and Oakland.

24. This Court has personal jurisdiction over each Defendant because each Defendant is present in the United States, including in this District, does business in the United States, including in this District, has registered agents in the United States, including in this District, may be found in the United States, including in this District, and are otherwise subject to the service of process provisions of 15 U.S.C. § 22.

III. THE PARTIES

25. Plaintiff Mayo Clinic is a Minnesota non-profit corporation with its principal place of business in Rochester, Minnesota. Mayo Clinic is the exclusive owner by express assignment of all antitrust claims arising from injuries caused by Defendants' misconduct as alleged herein to all subsidiaries and affiliates, including to the Mayo Foundation for Medical Education and Research (referred to collectively herein as "Mayo Clinic"). Mayo Clinic is a nationally recognized healthcare system with academic and research hospitals and healthcare centers across multiple states, including Minnesota, Florida, and Arizona. During the time period relevant to this action, Mayo Clinic purchased substantial quantities of Revlimid and later generic lenalidomide in the following ways: (i) directly from Defendants Celgene and BMS (through at least July 2021); (ii) via distributors and/or wholesalers, namely Cardinal Health (beginning in July 2021); and (iii) directly from Defendants Natco and Teva, as well as others (beginning in March 2023). As a result of Defendants' misconduct as alleged herein, Mayo Clinic paid more for Revlimid and generic lenalidomide than it would have paid in the absence of Defendants' misconduct and will continue to be charged supracompetitive prices for Revlimid and generic lenalidomide through at least January 2026.

26. Plaintiff LifePoint Corporate Services, General Partnership ("LifePoint") is a Delaware entity with its principal place of business in Brentwood, Tennessee. LifePoint is the exclusive owner by express assignment of all antitrust claims arising from injuries caused by Defendants' misconduct as alleged herein to all subsidiaries and affiliates (referred to collectively herein as "LifePoint"). LifePoint is a national healthcare system that includes multiple hospitals and health centers in more than twenty states across the country. During the time period relevant to this action, LifePoint purchased substantial quantities of Revlimid and later generic

lenalidomide via distributors and/or wholesalers, including AmerisourceBergen Corporation, among other sources. As a result of Defendants' misconduct as alleged herein, LifePoint paid more for Revlimid and generic lenalidomide than it would have paid in the absence of Defendants' misconduct and will continue to be charged supracompetitive prices for Revlimid and generic lenalidomide through at least January 2026.

27. Defendant Celgene Corporation. ("Celgene") is a Delaware corporation with its principal place of business in Summit, New Jersey. Celgene manufactures and markets Revlimid. Celgene is registered with the California Secretary of State as a foreign corporation and maintains a registered agent in California. Celgene is defined to include its managers, officers, employees, and agents acting on its behalf.

28. On or about November 2019, Celgene became a wholly-owned subsidiary of Defendant Bristol-Myers Squibb Company ("BMS"), a Delaware corporation with is principal place of business in New York, New York. BMS is registered with the California Secretary of State as a foreign corporation and maintains a registered agent in California. BMS also maintains a "robust presence in California" (according to its own website)[12] including the location of three research centers in the Northern District of California, as well as 863 employees with a total payroll of $473.4 million located in California, over $973 million in vendor relationships in California alone, and over 157 clinical trials at 439 clinical trial sites in California (including those involving Revlimid).[13] BMS is defined to include its managers, officers, employees, and agents acting on its behalf.

29. Defendant Natco Pharma Limited is an Indian drug manufacturer headquartered at Natco House, Road No. 2, Banjara Hills, Hyderabad-500, 034, India. Natco develops and markets drugs throughout the world, including in the United States and the Northern District of California. Natco is defined to include its managers, officers, employees, and agents acting on its behalf.

[12] *See California*, Bristol Myers Squibb, https://www.bms.com/assets/bms/us/en-us/pdf/california-fact-sheet.pdf (last visited Sept. 24, 2023).

[13] *Id.*

30. Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a Delaware corporation with its principal place of business in Parsippany, New Jersey. Teva is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd., an Israeli corporation. Teva is registered to do business within the State of California and has registered agents for service of process in California. Teva is defined to include its managers, officers, employees, and agents acting on its behalf. In August 2016, Teva acquired Watson and Watson's subsidiary, Arrow, Natco's marketing partners for generic lenalidomide, through its acquisition of Allergan plc's Actavis Generics.[14]

31. Defendant Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") is a New Jersey corporation with its principal place of business located in Princeton, New Jersey. Dr. Reddy's is a wholly-owned subsidiary of Dr. Reddy's Laboratories Ltd., an Indian pharmaceutical company. Dr. Reddy's is registered with the California Secretary of State as a foreign corporation and maintained a registered agent in California. Dr. Reddy's is defined to include its managers, officers, employees, and agents acting on its behalf.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The Market for Branded and Generic Drugs

1. Unique Characteristics of the Market for Brand Name Prescription Drugs

32. For most goods and products, the person or entity responsible for paying for the product is also the person or entity selecting the product. In this dynamic, the price of the product typically plays a significant role in the person or entity's choice of products and, consequently, manufacturers have an incentive to lower the prices of their products in order to compete with other similar products in that particular market. The market for prescription drugs noticeably departs from this norm.

33. Unlike other typical goods and products, prescription drugs (by their very nature) may only be dispensed pursuant to a doctor's prescription and licensed pharmacies may dispense

[14] *See Teva Completes Acquisition of Actavis Generics*, Teva (Aug. 2, 2016), https://www.tevapharm.com/news-and-media/latest-news/teva-completes-acquisition-of-actavis-generics/; *Watson Pharm., Inc. is Now Actavis, Inc.*, PR Newswire (Jan. 24, 2013), https://www.prnewswire.com/news-releases/watson-pharmaceuticals-inc-is-now-actavis-inc-188196701.html.

only the brand name drug or its AB-rated,[15] FDA-approved generic equivalent identified in the prescription.[16] The requirement of a prescription introduces a unique "disconnect" between the payment obligation and the product selection. The purchaser is obligated to pay for the prescription drug, but it is the doctor who chooses which product the purchaser will buy.

34. Brand manufacturers exploit this market "disconnect" by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products and doctors, who are not the ones ultimately paying for the drug, do not ask. Indeed, studies show that doctors are typically unaware of the relative costs of brand name pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a market in which price plays a comparatively unimportant role in product selection.

35. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. Reduced price elasticity, in turn, gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to raise price substantially above marginal cost is what economists and courts refer to as "market power."

36. The consequences of the "disconnect" in the market for brand name pharmaceuticals means that brand manufacturers are often allowed to gain—and maintain—unchecked market power.

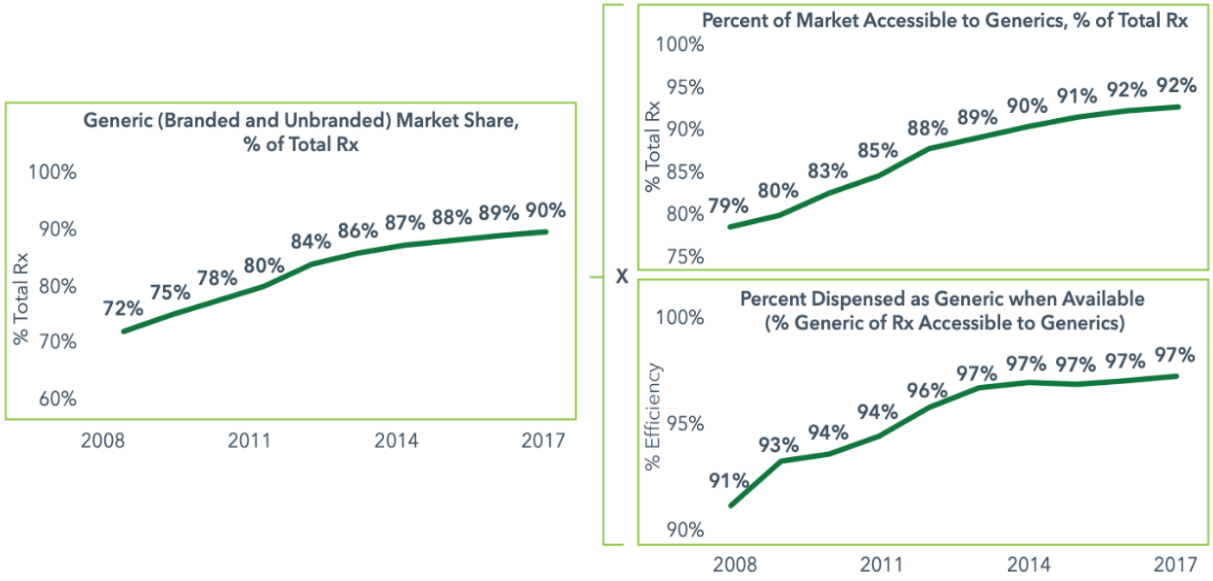
[15] A generic drug is considered bioequivalent or "AB-rated" if it contains the same API as the brand drug, is the same dosage and form, and exhibits a similar rate and extent of absorption as the brand product. *See* 21 U.S.C. § 355(j)(2)(A); FTC Amicus Br., 3-4, *Mylan Pharm., Inc. v. Celgene Corp.*, Case No. 14-CV-2094-ES-MAH, ECF No. 26-3 (hereinafter, "FTC Amicus Br.").

[16] Due to the cost savings that can be realized from generic drugs, state laws often require pharmacists to fill prescriptions with AB-rated generic versions of the drug prescribed when one is available.

2. *The Importance of Generic Drug Competition*

37. When there is no generic competition for a brand name drug, the brand manufacturer can set and maintain prices without losing sales. The ability to do this is the result of the brand name drug company's monopoly power over the market for that drug in both its brand and generic form. When an AB-rated generic is available, price competition is introduced. Formulary design and state generic substitution laws give purchasers a chance to substitute on the basis of price, and they do, as price is the only material difference between a brand and AB-rated generic version.

38. Typically, AB-rated generic versions of brand name drugs are priced significantly below their brand name counterparts. Within approximately a year after the first AB-rated generic is introduced into the market, the generic penetration rate (that is, the percentage at which pharmacies fill a prescription with an AB-rated generic over a brand name drug) is over 90%.[17]



[17] *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*, IQVIA Inst., at 14 (2018), https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022; *see, e.g.,* Jon Leibowitz, *"Pay for Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform* (Jun. 23, 2009), https://www.ftc.gov/sites/default/files/documents/public_statements/pay-delay-settlements-pharmaceutical-industry-how-congress-can-stop-anticompetitive-conduct-protect/090623payfordelayspeech.pdf.

Generic drug entry, therefore, realizes significant cost savings for drug purchasers, but it comes at the expense of brand drug manufacturers' profitability. In 2012 alone, the use of generic drugs generated an estimated $217 billion in total savings.[18]

39. In sum, generic competition enables purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand drug at a reduced price because the brand drug manufacturer's market power has been reduced and price elasticity has been introduced to the market for that particular drug.

40. Indeed, there is an incentive to choose the less expensive generic equivalent at every link in the prescription drug chain. From pharmaceutical wholesalers or distributors to group purchasing organizations to hospitals, healthcare systems, and retail pharmacies (the final step on the pharmaceutical supply chain before drugs reach the end user or patient), when the market operates as it should, each will opt to pay lower prices to acquire generic drugs than to acquire the corresponding brand name drug.

41. Generic competition enables purchasers like Plaintiffs to purchase a generic version of a brand name drug at substantially lower prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no generic drug that competes effectively with the brand name drug, and therefore, the brand name manufacturer can charge supracompetitive prices without losing sales. Given their acute knowledge of the effects of generic entry into a market, brand name manufacturers like Celgene and BMS have a strong incentive to delay such entry, including through the anticompetitive scheme detailed herein.

B. The Precariously Balanced Regulatory Scheme for Brand Name and Generic Drugs

1. Brand Name Drugs - NDAs, Patent Protection, and the Orange Book

42. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). *See* 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety

[18] FTC Amicus Br. at 5 (*citing* Generic Pharm. Ass'n, *Generic Drug Savings in the U.S.*, at 1 (5th ed. 2013).

and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

43. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." The manufacturer is required to list in the Orange Book any patents (1) that claim the approved drug or its approved uses; and (2) for which a "claim of patent infringement could reasonably be asserted if a person is not licensed by the owner engaged in the manufacture, use, or sale of the drug."[19] If any such patents issue after the FDA approves the NDA, the manufacturer must subsequently list them in the Orange Book within 30 days of their issuance.[20]

44. The FDA relies completely on the brand manufacturer's representations about patent validity and applicability, as it does not have the resources or authority to verify the validity or applicability of the manufacturer's patents. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

45. Once a brand manufacturer lists a patent in the Orange Book, it creates the possibility for the brand manufacturer to later sue a generic competitor for infringing the listed patent before the competitor has launched its product and, in doing so, trigger an automatic 30-month stay of FDA approval.

46. Not all patents that may claim or cover aspects of a drug product or its manufacture may be listed in the Orange Book; for example, patents that claim a process of making a drug, product packaging, aspects of a device used to deliver a pharmaceutical composition, and REMS programs do not meet the statutory and regulatory standard and cannot be properly submitted for listing in the FDA's Orange Book.

[19] 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(g)(7)(A)(iii).

[20] 21 U.S.C. §§ 355(b)(1) & (c)(2).

2. The Hatch-Waxman Act's Abbreviated Generic Drug Approval Process

47. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the "Hatch-Waxman Act."[21] The Hatch-Waxman Act seeks to balance both drug innovation and the promotion of competition between brand and generic drugs to lower drug prices.

48. To encourage innovation, the Hatch-Waxman Act gave branded drug manufacturers longer periods of market exclusivity for newly-approved products, which increased the financial returns to such manufacturers for investment in drug research and development. To promote price competition, the Hatch-Waxman Act established a new regulatory approval pathway for generic products to help ensure that generic drugs became available to the healthcare community more quickly following a drug's patent expiration.

49. The Hatch-Waxman Act encouraged faster approval for generic versions of branded drugs through the use of "abbreviated new drug applications" ("ANDA"s). An ANDA applicant may rely on the safety and efficacy evidence previously submitted by the branded drug manufacturer for the NDA if the ANDA demonstrates the proposed generic drug is both pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent"), *i.e.,* it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand name drug, and is absorbed at the same rate, and to the same extent, as the brand name drug. The FDA assigns oral-dosage-form generic drugs that are therapeutically equivalent to their brand name counterpart an "AB" rating.

50. Bioequivalence exists when the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart.[22] Bioequivalence is generally demonstrated via studies in which the proposed generic is compared to the Reference Listed Drug ("RLD," which is, in this instance, the brand name drug) in either *in vivo* (live) or *in vitro* (in a laboratory) studies. These studies

[21] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[22] 21 U.S.C. § 355(j)(8)(B).

require the ANDA applicant to have access to sufficient samples of the RLD to conduct the necessary comparisons. Without RLD samples, it is impossible to complete and file an ANDA for a proposed generic version of a drug.[23]

51. Only samples of the RLD approved by FDA and marketed in the United States may be used for bioequivalence testing purposes. A prospective ANDA applicant generally obtains samples by buying them, at market price, from either a drug wholesaler or distributor. Wholesalers and distributors are large companies that buy drugs from manufacturers for the purpose of reselling them to pharmacies or other entities. Generic companies are authorized to buy prescription drugs from distributors for bioequivalence testing purposes.

52. In 1983, before the Hatch-Waxman Act was enacted, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly every top-selling drug with expired patents had generic competition. Since the Hatch-Waxman Act was passed in 1984, generic drugs have moved from being less than 20% of prescriptions filled in the United States to nearly 91% of all prescriptions filled.[24] The FDA concluded that generic medications saved consumers approximately $338 billion in 2020 alone;[25] consumers have saved more than $2.6 trillion due to generic medications in the last decade.[26]

[23] The FDA suggests that generic drug manufacturers obtain between 1,500 and 5,000 units of the RLD to conduct sufficient bioequivalence studies. *See Statement from FDA Comm'r Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition*, FDA (May 17, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-agency-efforts-shine-light-situations-where-drug.

[24] U.S. Food & Drug Admin., *Office of Generic Drugs 2022 Annual Report*, at 1 (2022), https://www.fda.gov/media/165435/download.

[25] U.S. Food & Drug Admin., *Office of Generic Drugs 2021 Annual Report*, at 2 (2021), https://www.fda.gov/media/156066/download#page=6.

[26] *U.S. Generic & Biosimilar Med. Sav. Report*, Ass'n for Accessible Med., at 7 (Sept. 2022), https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf.

3. The Impact of Paragraph IV Certifications on Patent Holders and ANDA Applicants

53. As a counterbalance to the Hatch-Waxman Act's simplified ANDA process, the Hatch-Waxman Act seeks to further protect pharmaceutical innovation by providing brand manufacturers with the ability—by simply filing a patent infringement suit—to effectively obtain a preliminary injunction against a generic entrant's application. Once litigation has been initiated, a 30-month regulatory stay is triggered that bars the FDA from approving the generic manufacturer's ANDA until litigation resolves or the stay period expires.

54. In order to obtain FDA approval, an ANDA applicant must certify that the proposed generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Act, a generic manufacturer's ANDA must contain one of four certifications:

- Paragraph I Certification: No patent for the brand drug has been filed with the FDA;
- Paragraph II Certification: The patent for the brand drug has expired;
- Paragraph III Certification: The patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date; or
- Paragraph IV Certification: The patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product.[27]

55. When a generic manufacturer files a Paragraph IV Certification, it must notify the affected brand manufacturer and patent owner of the filing. If the patent holder files suit against the ANDA applicant within 45 days of receiving the Paragraph IV Certification ("Paragraph IV Litigation"), the Hatch-Waxman Act prevents the FDA from granting final approval to the ANDA until the *earlier* of (a) 30 months after the lawsuit is commenced, or (b) the court presiding over the patent infringement action rules that the patent is invalid or not infringed by the ANDA.[28] It is almost always the case that the 30-month period expires before the court rules, resulting in a 30-month automatic stay.

[27] 21 U.S.C. § 355(g)(2)(A)(vii).

[28] 21 U.S.C. § 355(j)(5)(B)(iii).

56. Until the stay is lifted (or the Paragraph IV Litigation is resolved by court order), the FDA may grant "tentative approval" of an ANDA but cannot authorize the generic manufacturer to market its product. The FDA may grant tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the Paragraph IV Litigation.

57. In addition to providing extra protections to the brand manufacturers and purported patent holders, the Hatch-Waxman Act also seeks to provide certain incentives to would-be generic entrants to be the first to file an ANDA containing a Paragraph IV Certification. The so-called "first-filer" (as distinguished from "later filers" and "authorized generics") will typically receive a period of protection from competition from other generic versions of the drug. For Paragraph IV Certifications made after December 2003, the first-filer receives 180 days of market exclusivity, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same branded drug. That is, when a first-filer submits a substantially complete ANDA with the FDA and certifies that the brand manufacturer's unexpired patents listed in the Orange Book are either invalid or not infringed by the generic, the FDA cannot approve later filers' ANDAs until that first-filer has been on the market for 180 days.

58. The 180-day window is often referred to as the first-filer's six-month or 180-day "exclusivity"; this is a bit of a misnomer because a brand manufacturer (like Celgene and BMS) can launch an authorized generic ("AG") at any time, even prior to the first-filer's generic entry. An AG is an approved brand name drug, like Revlimid, that although marketed without the brand name on its label, is the exact same drug product as the branded product. Through an AG, brand manufacturers can enjoy the competitive benefits of marketing both their branded and a "generic" drug, capturing sales from customers interested in either.[29] Thus, brand manufacturers frequently launch AGs in response to generic entry in order to recoup some of the sales they would otherwise lose entirely to the generic entrant.

59. As a practical matter, AGs are the only means by which brand name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand name

[29] An AG thus does not need to go through the ANDA process because it is the exact same drug product as the branded product.

manufacturers generally do not reduce the price of their brand drugs in response to the entry of AB-rated generics. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the brand drug at the same rate at which it was raised prior to generic entry.

60. This 180-day period of exclusivity can prove extremely valuable, possibly worth several hundred million dollars, to the first-filer. This is because, as highlighted above, the price of generic drugs drops with every additional entrant into the generic drug's market. But, competition from an AG during the 180-day exclusivity period substantially reduces the price of both the first-filer's generic drug and the AG and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand name manufacturer. Both of these effects reduce the first-filer's revenues and profits. In its study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011), the Federal Trade Commission ("FTC") found that AGs capture a significant portion of sales, reducing the revenues generated by the first-filer's generic product by approximately 50% during the 180-day exclusivity period.

61. A first-filer that informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing forms of generics.

62. Conversely, the first-filer can also help the brand manufacturer "game the system" if it agrees not to begin marketing its generic drug, thereby delaying the start of the Hatch-Waxman Act's 180-day period of generic market exclusivity. This tactic creates a powerful "bottleneck" because later generic applicants cannot launch their competing products until the first-filer's 180-day exclusivity has either elapsed or is forfeited.

4. The Contestability of Patents and the Impact on Pharmaceuticals

63. A patent may be deemed valid or invalid, infringed or not infringed, and enforceable or unenforceable. Simply owning a patent does not entitle the patent owner to

exclude others. Patents are routinely invalidated or held unenforceable, either upon reexamination or *inter partes* proceedings by the USPTO, by court decision, or by jury verdict.

64. At all times, a patent holder bears the burden of proving infringement. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

65. A patent is invalid or unenforceable when: (i) the disclosed invention is obvious in light of earlier prior art; (ii) when an inventor, an inventor's attorney, or another person involved with the application fails to disclose material information known to that person to be material or submits materially false information to the PTO during prosecution with intent to mislead or deceive the USPTO; and/or (iii) when a later-acquired patent is not distinct from the invention claimed in an earlier patent (and no exception applies).

66. In these circumstances, the USPTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or omissions on which the USPTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

67. In practice, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generic manufacturers prevailed in 73% of Hatch-Waxman Act patent litigation cases resolved on the merits between 1992 and 2002. An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic manufacturer wins 74% of the time.

5. The FDA's REMS Program and its Abuse by Brand Manufacturers

68. The Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, more commonly known as the Controlled Substances Act, was enacted by Congress to improve

the manufacturing, importation and exportation, distribution, and dispensing of controlled substances.[30] Among other regulations to manage risks related to pharmaceutical products, the Controlled Substances Act permitted the FDA to impose disclosure warnings and other labelling requirements on pharmaceutical packaging.[31]

69. The FDA's work with manufacturers to develop risk management programs for drugs with dangerous side effects continued in the following decades. In the early 2000s, the FDA established Risk Minimization Action Plans ("RiskMAPs") for approved products. When a drug has unusual risks but also has unusual benefits, the manufacturer may voluntarily implement a RiskMAP.

70. By 2007, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"),[32] which permitted the FDA to formalize the creation of a Risk Evaluation and Mitigation Strategies ("REMS") program for monitoring pharmaceuticals with a high potential for serious adverse effects.[33] REMS applies only to specific pharmaceutical drugs, but can apply to brand name or generic drugs.[34]

71. In practice, a REMS program is a safety strategy that manages a known or potential serious risk associated with a particular pharmaceutical and enables patients to have access to such pharmaceuticals by managing their safe use.

72. Under the law, a REMS may be required by the FDA as part of the approval of a new product, or for an approved product when new safety information arises. REMS elements can include a variety of safeguards, including medication guides, patient package inserts, and/or restrictions on the distribution of the drug. Since their implementation, REMS have been

[30] 21 U.S.C. § 801, *et seq*.

[31] *Id.* at § 825.

[32] 21 U.S.C. § 301, *et seq.*

[33] *Id.* at § 355-1.

[34] *See id.*

increasingly common in FDA's approval process; roughly 40% of new FDA approvals are subject to REMS programs.

73. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication. The FDA's authority to condition drug approval on the implementation of REMS is not intended to make drugs (or drug samples) less available for appropriate use. To the contrary, FDAAA § 355-1(f)(8) makes clear that a brand manufacturer is prohibited from using REMS to "block or delay approval of" a generic drug application.[35] The FDAAA does not restrict the sale of REMS-subject drugs to generic manufacturers that will use those drugs in controlled bioequivalence testing, nor does it give an NDA holder the right to interfere with a competitors' ability to purchase necessary drug samples from third parties.

74. Notwithstanding the explicit directives of the FDAAA, brand manufacturers continue to use REMS programs to delay competition by denying generic and biosimilars manufacturers access to samples of branded drug products, which are necessary for bioequivalence testing. Without access to these samples, generic approvals are blocked and would-be generic competitors are excluded from the market. According to a July 2014 study conducted by Matrix Global Advisors, the ongoing abuse of REMS and REMS-like programs costs the U.S. healthcare system at least $5.4 billion annually.[36]

75. In December 2019, to combat the most common abuses of REMS programs while maintaining necessary safety protections for patient safety and public health, Congress passed the "Creating and Restoring Equal Access to Equivalent Samples Act of 2016" ("CREATES Act").[37] The legislation was intended to strengthen the Hatch-Waxman Act by establishing a process for generic drug producers to bring their product to the marketplace. Under the CREATES Act,

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[35] *Id.* at § 355-1(f)(8).

[36] Alex Brill, *Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry*, Matrix Global Advisors, 1 (Jul. 2014), https://getmga.com/wp-content/uploads/022/04/REMS_Study_July.pdf (analyzing the savings as to 40 pharmaceutical products).

[37] Material portions of CREATES were incorporated into the Further Consolidated Appropriations Act, 2020, Pub. L. 116-94.

qualifying developers of generic drugs can bring a civil action against branded drug manufacturers that refuse "to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms."[38] The Act imposes substantial penalties if a branded company is determined to have acted in bad faith. If the generic developer prevails, the court *must* order the branded drug manufacturers to provide sufficient quantities of samples of the drug on commercially reasonable terms "without delay", award attorneys' fees and costs, and award a monetary amount "sufficient to deter" a defendant brand manufacturer from withholding samples to other companies developing generics in the future.[39]

76. The CREATES Act establishes a prospective counterbalance to monopolistic schemes by brand manufacturers who abuse the REMS process to unlawfully monopolize the market for a drug by excluding generic competition beyond the period and scope afforded by a lawfully obtained patent, but it does not provide a remedy for past REMS abuse.[40]

6. Misuse of Citizen Petitions By Brand Manufacturers

77. Another strategy used by brand drug manufacturers to delay price-reducing generic competition involves "citizen petitions" filed with the FDA. Section 505(q) of the FDCA creates a mechanism to file a petition with the FDA requesting that the agency take, or refrain from taking, any form of administrative action relating to a pending drug application.[41] In theory, citizen petitions allow any party to raise safety or effectiveness concerns with drugs the FDA is

[38] 21 U.S.C. § 355-2(b)(1).

[39] 21 U.S.C. § 355-2(b)(4).

[40] Senator Patrick Leahy's (D-VT) committee comments echo the misconduct alleged against Celgene here: "The first delay tactic addressed by the CREATES Act involves withholding of drug samples that generic manufacturers need to gain regulatory approval. Federal law requires generic competitors to prove that their low-cost alternative is equally safe and effective as the brand name drug with which they wish to compete. Unfortunately, some brand name companies are refusing to provide samples of their product to generic companies for them to make the necessary comparison. This simple delay tactic uses regulatory safeguards as a weapon to block competition." Hr'g Before the S. Judiciary Comm. Subcomm. on Antitrust, Competition Policy and Consumer Rights on "The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition," Statement of Senator Patrick Leahy (June 21, 2016) https://www.judiciary.senate.gov/download/06-21-16-leahy-statement-2.

[41] 21 U.S.C. § 355(q).

considering for approval. In practice, however, the regulatory mechanism is used primarily by brand manufacturers to delay generic approval and unlawfully extend the monopolies on their brand drugs.

78. Because the FDA's primary concern is safety, regardless of how frivolous or questionable a petition might appear, the FDA reviews and responds to each and every petition. It is also standard practice for the FDA to withhold ANDA approval until it has completed its research into and response to each citizen petition.

79. It is this automatic stay of ANDA approval that makes petitions by branded manufacturers an increasingly common tactic used to delay generic competition, even if the petition is later found to be baseless. Recent studies have shown that more than 90% of 505(q) citizen petitions are filed by brand name pharmaceutical companies. And in turn, an equal percent of those petitions are ultimately rejected by the FDA.

80. In short, citizen petitions are not being used as intended: to raise valid scientific or safety concerns. Instead, the mechanism has been manipulated by brand name manufacturers to further delay the approval of generic competition.

C. What Competition in the Drug Markets *Should* Look Like

81. Generic versions of brand name pharmaceutical drugs contain the same active ingredient(s) as the brand name drug and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between generics and their corresponding brand versions is the price. Because generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a branded product and its generic version, or among generic versions, is price. Typically, generics are 50% to 80% (or more) less expensive than their brand counterparts when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings for drug purchasers.

82. Since the passage of the Hatch-Waxman Act, every state has adopted drug product selection laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician specifically directs that substitution is

not permitted). Substitution laws and other institutional features of pharmaceutical distribution and health insurance means that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic hits the market, it quickly captures sales of the corresponding brand drug, often 80% or more of the market, within the first six months after entry.

1. The First AB-Rated Generic is Priced Below the Brand Drug

83. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[42] Every state either requires or permits that a prescription written for the brand be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand. Generic sales at lower prices drive a reduction in the average price paid for the drug at issue.

84. During the 180-day exclusivity period, the first-filer is the only ANDA-approved generic manufacturer on the market (though the brand's AG can be, and often is, on the market simultaneously). In the absence of competition from other generics, during the 180-day exclusivity period, a first-filer generic manufacturer generally makes about 80% of all of the profits that it will ever make on the product.

2. Later Generic Drugs Drive Prices Down Further

85. Once other generic competitors enter the market, the competitive process accelerates and multiple generic manufacturers typically compete vigorously with each other over price, which drives prices down toward marginal manufacturing costs.[43]

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[42] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, at ii-iii, vi, 34 (2011), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf ("FTC 2011 AG Study").

[43] *See, e.g.,* Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 INT'L J. INDUS. ORG. 930 (2008); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J. L. & ECON. 311 (2000).

86. In a 2011 report by the FTC issued at the request of Congress, the FTC found that generics captured 80% or more of sales in the first six months regardless of the number of generic entrants.[44] In the end, the brand manufacturer's sales decline to a small fraction of their level before generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[45]

3. Even AGs Compete on Price

87. Any 180-day exclusivity period applies to a first-filer ANDA, not to products sold under the authority of the original NDA. As a result, the 180-day exclusivity does not prevent a brand manufacturer from marketing and selling an AG at any time or from licensing another company to do so.

88. The FDA determined that allowing brand manufacturers to introduce AGs during the 180-day exclusivity period is consistent with the "fundamental objective of the Hatch-Waxman [A]mendments" to encourage competition and, as a result, "lower prices in the pharmaceutical market."[46] The FDA reasoned that if a brand releases an AG at a reduced price during the 180-day exclusivity period, "this might reasonably be expected to diminish the economic benefit" to the generic first-filer by increasing competition and causing the generic to "reduc[e] the substantial 'mark-up' [generics] can often apply during the [180-day] period."[47] Such competition, and the resulting price decreases, work to benefit drug purchasers.

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[44] FTC 2011 AG Study at 66-67.

[45] *See* U.S. Food & Drug Admin., *What Are Generic Drugs?* (Aug. 24, 2017), https://www.fda.gov/drugs/generic-drugs/what-are-generic-drugs.

[46] U.S. Food & Drug Admin., Opinion Letter re: Citizen Petition Docket Nos. 2004P-0075/CP1 & 2004P-0261/CP1, at 12 (Jul. 2, 2004), https://www.regulations.gov/document/FDA-2004-P-0400-0003.

[47] *Id.* at 12.

89. Brand manufacturers recognize the significant economic advantages of releasing their AGs to compete with the first-filer generic during the 180-day exclusivity period. One study noted that "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[48]

90. Competition from an AG substantially reduces drug prices and the revenues of the first-filer generic, especially during the 180-day exclusivity period.

91. A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[49]

92. The FTC similarly found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by about 50% on average.[50] The first-filer generic makes much less money when it faces competition from an AG because (i) the AG takes a large share of unit sales away from the first filer; and (ii) the presence of the AG causes prices, particularly generic prices, to decrease.

93. AGs are therefore a significant source of price competition. In fact, they are the only potential source of generic price competition during the first-to-file generic manufacturer's 180-day exclusivity period. All drug industry participants recognize this. A brand industry group sponsored a study which concluded that the presence of an AG causes generic prices to be more approximately 16% lower.[51]

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[48] Kevin A. Hassett & Robert J. Shapiro, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals*, Sonecon, at 3 (2007), http://www.sonecon.com/docs/studies/050207_authorizedgenerics.pdf.

[49] Ernst R. Berndt, *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 HEALTH AFFAIRS 790, 796 (2007).

[50] FTC 2011 AG Study at 139.

[51] *Authorized Generics: An Interim Report*, FTC, at ch. 1, 1-2 (Jun. 2009), https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authorizedgenericsreport.pdf.

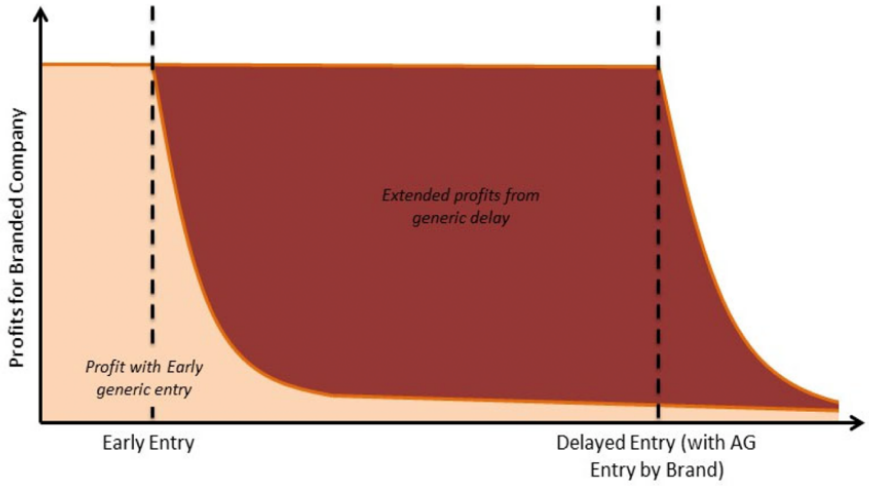
D. What Happens When the Hatch-Waxman Act Regulatory Structure is Manipulated in Order to Impede Competition

94. The brand manufacturer of a pharmaceutical product without generic competition gets all of the profits on all of the unit sales. In this circumstance, brand manufacturers can usually sell their drug for far more than the marginal cost of production, generating profit margins of 70% or more. The ability to set price so much above cost is one indication that the brand firm is exercising market power.

95. Competition from generic firms constricts the brand manufacturer's market power and delivers enormous savings to drug purchasers. Competition converts what formerly were monopoly profits into purchaser savings.

96. While brand manufacturers and first-filer generic manufacturers are typically marketplace competitors, they have a collective interest in preventing robust competition from other generic manufacturers—competition that severely erodes prices—from breaking out. If the brand and first-filer generic work together to prevent or delay such competition, they can keep the profit margins high and split the resulting excess profits between themselves. In other words, by stifling competition, the brand manufacturer and first-filer generic manufacturer can maintain high prices, protect their profits, and split between themselves the enormous savings that increased generic competition would have delivered to drug purchasers.

97. The following figure compares the impact on a brand manufacturer's profits between (i) a situation where it settles a patent lawsuit on the merits (*i.e.,* with only an agreed-upon entry date and without a pay-off to the generic company); and (ii) a situation where it settles the lawsuit with a large, unjustified payment to the generic manufacturer. In the former situation, the agreed-upon entry date for the generic is earlier and the brand manufacturer's profits are thus greatly reduced. In the latter situation, the agreed entry date is later and the brand manufacturer's profits increase significantly.



98. In order for such an anticompetitive pact to work, brand and generic manufacturers need a means by which to divide between them the ill-gotten gains—the increased profit to the detriment of drug purchasers—that delayed competition makes possible. The generic manufacturer has no incentive to refrain from competing unless it shares in the brand profits from the delay. To make this happen, some form of payoff from the brand manufacturer is required, resulting in agreements that are commonly referred to as "pay-for-delay," "exclusion payments," or "reverse payments."

99. In the presence of a first-filer's 180-day exclusivity period, the brand manufacturer's (unlawful) payoff to the first-filer also delays other generic manufacturers from marketing their products because none of the later filers can enter until the first-filer's 180-day exclusivity period has run.

100. Later ANDA filers can expect lower profits than a first-filer because they may have little or no expectation of any form of market exclusivity. By the time they enter the market, there is at least the brand and one other generic on the market and, thus, the drug has already been, or is on its way to being, commoditized. As a result, in a pay-for-delay agreement, later-filing generics may require less of a payment not to compete. Under these unlawful arrangements, the brand shares some of its supracompetitive profits with the later-filing generics, and in exchange the later-filing generics drop their patent challenges and accept a later, agreed-upon entry date.

101. Pay-for-delay agreements are fundamentally anticompetitive and contrary to the goals of the Hatch-Waxman statutory scheme. They extend the brand manufacturer's monopoly by blocking access to more affordable generic drugs and forcing purchasers to buy expensive brands instead. Indeed, the FTC estimates that pay-for-delay agreements cost taxpayers, insurance companies, and consumers approximately $35 billion between 2010 and 2020.[52]

1. Abuse of the United States Patent System and "Pay-for-Delay" Settlements

102. Because the Hatch-Waxman regulatory scheme automatically delays approval of an ANDA whenever a brand name manufacturer sues the potential generic competitor for alleged patent infringement, brand name manufacturers frequently take aggressive positions in listing patents in the Orange Book, and then bring patent lawsuits against any generic competitor that files an ANDA with a Paragraph IV Certification. Brand name manufacturers often sue generic manufacturers simply to delay generic competition rather than to enforce valid patents against infringing products.

103. In connection with the resolution of patent litigation arising out of Paragraph IV Certifications, some brand name manufacturers have entered into settlements in which the brand name manufacturer pays off its generic competitors in exchange for a delay in generic competition. As described above, these exclusion payment agreements among horizontal competitors not to compete are commonly known as "pay-for-delay" or "reverse-payment agreements." Brand and generic manufacturers execute exclusion payment agreements as purported settlements of patent infringement lawsuits that brand manufacturers file against generic manufacturers, often with confidentiality restrictions to keep their anticompetitive terms from public view. The brand name manufacturer preserves increased profits by keeping its monopoly intact via a payment of some of the monopoly profits to the generic manufacturer, which in turn agrees to delay marketing its product. The Supreme Court held that such

[52] *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, FTC, at 2 (Jan. 2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

agreements are subject to antitrust scrutiny under the rule of reason in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013).

104. Initially, reverse-payment agreements took the form of a straight cash payment from the brand name manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and lawsuits, brand name manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive character of their agreements. Because the profits to be gained by delaying generic competition are so great, however, reverse-payment agreements remains attractive.

105. These agreements often involve the brand manufacturer agreeing not to bring an AG to market. Given the significant negative impact of an AG on the first-filing generic's revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an AG has tremendous economic value to a first-filer generic manufacturer. Such agreements compensate the generic for delaying entry of its generic drug by completely eliminating competition between the first-filer's generic and the AG, giving the first-filer a monopoly on generic sales during their 180 day exclusivity period.

2. Using Anticompetitive "Acceleration" or "Most-Favored Entry" Clauses to Further Delay Competition

106. "Acceleration" clauses" are another weapon in the pharmaceutical monopolist's arsenal to delay generic entry. They often take the form of a "most-favored entry" ("MFE") clause, which allows a settling generic to enter the market earlier than otherwise agreed if certain events occur, including entry by another generic. When used to settle Hatch-Waxman Act litigation, MFE clauses disincentivize later-filing generic manufacturers from seeking to enter prior to another settling generic through litigation. Such clauses constitute a disincentive to later generic filers because they accelerate the settling generic's entry date and thereby deprive the later generic of any *de facto* exclusivity that it might otherwise be able to obtain by entering as a result of successful litigation. An acceleration clause also transfers value to the settling generic in two ways: the contingent right to accelerate generic entry increases expected profits and any deterrent effect on later filers protects the settling generic's market position. Because an MFE

clause creates value for the settling generic, it can be used to induce the settling generic to accept a later entry date.

107. The purpose and effect of an MFE clause is to dramatically reduce any other generic manufacturer's incentive to try to enter the market before a settling generic with an MFE. Absent the clause, other generic manufacturers would have an incentive to enter the market as soon as they were able in order to enjoy a substantial period of *de facto* exclusivity as the only ANDA-based generic product on the market. An MFE clause delays generic entry by, *inter alia*, eliminating this possible exclusivity because, even if the later generic succeeds in establishing its right to enter the market through litigation, it will face generic competition from the accelerated generic settler.

108. The Chairman and CEO of Apotex, Inc.—one of the largest generic manufacturers in the world—twice testified to Congress that "acceleration" clauses represent "the primary anticompetitive aspects of settlements" because they "eliminate any incentive for a subsequent filer to continue to litigate for earlier market entry."[53] The clauses both induce prospective generic competitors to accept later entry dates and deter others from challenging weak patents:

> [N]o subsequent filer is going to take up the patent fight knowing it will get nothing if it wins. Consumers are the biggest losers under this system. If subsequent filers do not have the incentive to take on the cost of multimillion patent challenges these challenges will not occur. Weak patents that should be knocked out will remain in place, unduly blocking consumer access to generics. The challenges to brand patents by generic companies that Hatch-Waxman was designed to generate will decrease. And settlements that delay consumer access to the generic will, in turn, increase.[54]

[53] Protecting Consumer Access to Generic Drugs Act of 2007: Hr'g on H.R. 1902 before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy & Commerce, 110th Cong., at 65, 67 (May 2, 2007) (statement of Bernard Sherman, CEO, Apotex, Inc.), http://www.gpo.gov/fdsys/pkg/CHRG-110hhrg38992/pdf/CHRG-110hhrg38992.pdf.

[54] Protecting Consumer Access to Generic Drugs Act of 2009: Hr'g on H.R. 1706 before the Subcomm. On Commerce, Trade, and Consumer Protection of the H. Comm. On Energy & Commerce, 111th Cong., at 218 (Mar. 31, 2009) (statement of Bernard Sherman, CEO, Apotex, Inc.), http://www.gpo.gov/fdsys/pkg/CHRG-111hhrg67822/pdf/CHRG-111hhrg67822.pdf.

109. Contrary to their name, "acceleration" clauses do not in fact accelerate generic entry—they delay it. The evidence for this is conclusive. A recently published study analyzing empirical pharmaceutical settlement data concluded that "[a]n acceleration clause paired with the 180-day exclusivity period appears to effectively deter other generics and, at least in the instances we observed, never to have resulted in an actual 'accelerated' entry."[55] The study revealed:

> Among the 54 cases in which the first filer retained sole rights to the 180-day exclusivity period, there were no cases of early generic entry. In other words, there were no cases in which the first filer's entry was accelerated, and there were no cases in which a different generic entered before the entry date set in the first filer's settlement.[56]

110. Another type of acceleration clause—and the one utilized here by Celgene and BMS—is a Most-Favored-Entry-*Plus* clause or "MFEP." An MFEP provides that the brand manufacturer will guarantee the settling generic a 180-day period of exclusivity and that no other subsequent settlement will violate that exclusivity.[57]

111. The purpose and effect of an MFEP, like an MFE, is to pay off the first-filer to get its agreement to delay its entry into the market. MFEPs also deter second filers from trying to enter the market before the first-filer. Absent the MFEP, second filers could use their own challenges to the brand manufacturer's patents as leverage to negotiate from the brand manufacturer a license to enter the market before the first-filer, thereby enjoying a substantial period where it would have the only generic product on the market.

V. DEFENDANTS' ANTICOMPETITIVE CONDUCT

A. Celgene's Excessive Patents on Both Thalidomide and Lenalidomide

112. Beginning in the 1950's, thalidomide was marketed as a sleeping pill and anti-morning-sickness pill for pregnant women. Unfortunately, thalidomide was discovered to be a

[55] Keith M. Drake & Thomas G. McGuire, *Generic Entry Before the Agreed-Upon Date in Pharmaceutical Patent Settlements*, 16 J. COMPETITION L. & ECON., 2, 194 (Jun. 2020).

[56] *Id.*

[57] Aylin Sertkaya, Ph.D., Andreas Lord, M.S., & Clara Berger, *Cost of Generic Drug Development and Approval*, U.S. Dep't Health & Human Svcs. Office of the Assistant Sec'y of Plan. And Evaluation, 60 (Dec. 31, 2021), https://aspe.hhs.gov/sites/default/files/documents/20e14b66420440b9e726c61d281cc5a5/cost-of-generic-drugs-erg.pdf.

teratogen, that is, when consumed by pregnant women, thalidomide caused life-threatening fetal deformities and birth defects. Other adverse effects included nerve damage to the patient.

113. Thalidomide was thereafter banned worldwide. The United States ban was in place until July 16, 1998, when FDA approved Celgene's December 20, 1996 NDA 20-785 for Thalomid, its branded version of thalidomide. FDA approved Thalomid only as a treatment for ENL, a form of leprosy.[58] To mitigate fetal exposure to the drug, FDA conditioned its Thalomid approval on Celgene's use of the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S.") distribution program (a precursor to REMS, which did not yet exist), in which patients were required to review educational materials, register with the program, and agree to program restrictions. FDA noted in its Thalomid NDA approval "[t]hat current restrictions strike a balance between the need to prevent fetal exposure to the drug and the need to make the drug available without extraordinary burdens on patients and prescribers."

114. After FDA codified its REMS distribution program, FDA approved Celgene's supplemental NDA containing a proposed REMS program for Thalomid on August 3, 2010.

115. Celgene filed, prosecuted, and listed in the Orange Book one patent for the Composition of Matter for Thalomid: Patent No. 7,230,012 (the "'012 Patent,") which was first filed with the USPTO in June 2003. Celgene filed, prosecuted and listed a total of fourteen patents related to the S.T.E.P.S. and/or REMS programs for controlling Thalomid, and later Revlimid, distribution: Patent Nos. 6,045,501 (the "'501 Patent"); 6,561,976 (the "'976 Patent"); 6,908,432 (the "'432 Patent"; 7,874,984 (the "'984 Patent"); 8,204,763 (the "'763 Patent"); 8,589,188 (the "'188 Patent"); 6,315,720 (the "'720 Patent"); 6,561,977 (the "'977 Patent"); 6,755,784 (the "'784 Patent"); 6,869,399 (the "'399 Patent"); 7,141,018 (the "'018 Patent"); 7,959,566 (the "'566 Patent"); 8,315,886 (the "'886 Patent"); and 8,626,531 (the "'531 Patent"), all of which were filed with the USPTO between August 1998 and August 2012.

116. Revlimid is an immunomodulatory agent that works against cancer cells by affecting the immune system. It is a thalidomide analogue manufactured and marketed by

[58] Thalomid was later approved in 2006 to treat Multiple Myeloma ("MM"), subject to a restricted distribution system.

Celgene and later BMS. On April 7, 2005, Celgene submitted NDA 21-880 to FDA, which provides for the use of Revlimid to treat patients with transfusion-dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5 q cytogenetic abnormality with or without additional cytogenetic abnormalities. On December 27, 2005, FDA approved Revlimid for this indication. FDA granted Celgene five-year market exclusivity for Revlimid as a new chemical entity ("NCE") until December 27, 2010.

117. Revlimid is subject to a REMS distribution program, which initially was known as RevAssist. The primary goal of the RevAssist program is to prevent fetal exposure to Revlimid, which as a thalidomide analog, is also a teratogen. FDA noted in its December 27, 2005 letter to Celgene that RevAssist is "an important part of the post-marketing risk management for Revlimid®."

118. In total, Celgene filed, prosecuted, and listed 30 patents in FDA's Orange Book as claiming Revlimid.

119. The Orange Book-listed patents included the '517 Patent, which was first filed with the USPTO in July 1996, and two polymorph patents, Patent Nos. 7,465,800 (the "'800 Patent") and 7,855,217 (the "'217 Patent"), first filed with the USPTO in September 2004 and December 2008, respectively (the "Polymorph Patents"). As relevant here, a polymorph is a compound that can exist in two or more crystalline structures.

120. Celgene also filed, prosecuted, and listed patents in relation to the RevAssist program for controlling Revlimid distribution: the '501 Patent, the '976 Patent, the '432 Patent, the '763 Patent, the '188 Patent, the '720 Patent, the '977 Patent, the '784 Patent, the '886 Patent, and the '531 Patent, all of which were filed with the USPTO between August 1998 and August 2012.

121. Celgene also filed, prosecuted, and listed ten patents related to the dosage and methods of use for Revlimid: Patent Nos. 7,189,740 (the "'740 Patent,"); 7,968,569 (the "'569 Patent"); 7,468,363 (the "'363 Patent"); 8,741,929 (the "'929 Patent"); 8,404,717 (the "'717 Patent"); 8,648,095 (the "'095 Patent"); 9,056,120 (the "'120 Patent"); 8,530,498 (the "'498

Patent"); 9,101,621 (the "'621 Patent"); and 9,101,622 (the "'622 Patent"), all filed with the USPTO between April 2003 and September 2014.

122. Below is a chart summarizing Celgene's patent protection fortress:

Patent	Number	Date Filed	Date Issued	Expiration Date	Description	Drug(s)
Composition of Matter						
'517 Patent	5,635,517	24-Jul-96	3-Jun-97	4-Oct-19	Method of reducing TNFα levels with amino substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxo-and 1,3-dioxoisoindolines	Revlimid
'012 Patent	7,230,012	30-Jun-03	12-Jun-07	9-Dec-23	Pharmaceutical compositions and dosage forms of thalidomide	Thalomid
Polymorph						
'800 Patent	7,465,800	3-Sep-04	16-Dec-08	27-Apr-27	Polymorphic forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
'217 Patent	7,855,217	15-Dec-08	21-Dec-10	24-Nov-24	Polymorphic forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
REMS						
'501 Patent	6,045,501	28-Aug-98	4-Apr-00	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid Pomalyst[59]
'976 Patent	6,561,976	26-Sep-01	13-May-03	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid Pomalyst
'432 Patent	6,908,432	22-Jan-04	21-Jun-05	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid Pomalyst
'984 Patent	7,874,984	12-Apr-05	25-Jan-11	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other	Thalomid

[59] Pomalyst (pomalidomide) is, like Revlimid (lenalidomide), a thalidomide analogue that is manufactured by Celgene/BMS. Also, like Revlimid and Thalomid, Pomalyst is used to treat individuals with multiple myeloma. Pomalyst also treats AIDS-related Kaposi sarcoma.

					contraindicated individual to the drug	
'763 Patent	8,204,763	13-Dec-10	19-Jun-12	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid Pomalyst
'188 Patent	8,589,188	17-May-12	19-Nov-13	28-Aug-18	Methods for delivering a drug to a patient while preventing the exposure of a foetus or other contraindicated individual to the drug	Thalomid Revlimid Pomalyst
'720 Patent	6,315,720	23-Oct-00	13-Nov-01	23-Oct-20	Methods for delivering a drug to a patient while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug	Thalomid Revlimid Pomalyst
'977 Patent	6,561,977	27-Sep-01	13-May-03	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid Pomalyst
'784 Patent	6,755,784	7-Mar-03	29-Jun-04	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid Pomalyst
'399 Patent	6,869,399	22-Jan-04	22-Mar-05	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
'018 Patent	7,141,018	3-Jan-05	28-Nov-06	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
'566 Patent	7,959,566	19-May-06	14-Jun-11	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
'886 Patent	8,315,886	13-Dec-10	20-Nov-12	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be	Thalomid Revlimid Pomalyst

					contraindicated	
'531 Patent	8,626,531	22-Aug-12	7-Jan-14	23-Oct-20	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid Revlimid Pomalyst
Dosing						
'740 Patent	7,189,740	11-Apr-03	13-Mar-07	11-Apr-23	Methods of using 3-(4-amino-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6- dione for the treatment and management of myelodysplastic syndromes	Revlimid
'569 Patent	7,968,569	15-May-03	28-Jun-11	7-Oct-23	Methods for treatment of multiple myeloma using 3-(4- amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
'363 Patent	7,468,363	8-Apr-05	23-Dec-08	7-Oct-23	Methods for treatment of cancers using 3-(4-amino-1- oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
'929 Patent	8,741,929	19-Nov-09	3-Jun-14	8-Mar-28	Methods using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2- yl)-piperidine-2,6-dione for treatment of mantle cell lymphomas	Revlimid
'406 Patent	8,492,406	7-Apr-10	23-Jul-13	11-Dec-24	Methods for treatment of follicular lymphoma using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
'717 Patent	8,404,717	24-Mar-11	26-Mar-13	11-Apr-23	Methods of treating myelodysplastic syndromes using lenalidomide	Revlimid
'095 Patent	8,648,095	5-Jun-12	11-Feb-14	15-May-23	Methods for treating multiple myeloma using 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)-piperidine-2,6-dione in combination with proteasome inhibitor	Revlimid
'120 Patent	9,056,120	13-Mar-13	16-Jun-15	11-Apr-23	Methods of treating myelodysplastic syndromes with a combination therapy using lenalidomide and azacitidine	Revlimid
'498 Patent	8,530,498	8-Apr-13	10-Sep-13	15-May-23	Methods for treating multiple myeloma with 3-	Revlimid

					(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)piperidine-2,6-dione	
'730 Patent	9,155,730	26-Mar-14	13-Oct-15	15-May-23	Methods for treating non-hodgkin's lymphoma with 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)piperidine-2,6-dione in combination with a second active agent	Revlimid
'621 Patent	9,101,621	17-Apr-14	11-Aug-15	15-May-23	Methods for treating multiple myeloma with 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione after stem cell transplantation	Revlimid
'622 Patent	9,101,622	10-Sep-14	11-Aug-15	15-May-23	Methods for treating newly diagnosed multiple myeloma 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione in combination with dexamethasone	Revlimid
'238 Patent	9,393,238	09-Dec-14	19-Jul-16	15-May-23	Methods for treating non-hodgkin's lymphoma with 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)piperidine-2,6-dione in combination with a second active agent	Revlimid

123. Celgene obtained other patents related to thalidomide and its analogs but did not list them in the Orange Book.[60] Unlisted patents are not meaningful barriers to generic entry. A brand company does not have standing to sue, and thus litigate on the merits, a would-be competitor for allegedly infringing an unlisted patent *before* the competitor has actually sold its generic product. Nor do unlisted patents trigger an automatic 30-month stay of FDA approval for the competitor's ANDA.[61] Regardless, as part of its anticompetitive conduct, Celgene filed

[60] That Celgene did not submit these patents for listing in the Orange Book is a concession that they did not meet the statutory standard for listing in the Orange Book or for asserting against a generic company in paragraph IV Hatch Waxman Act litigation (which triggers the powerfully anticompetitive 30-month stay). These include U.S. Patent numbers 7,977,357 (the "'357 Patent"), 8,431,598 (the "'598 Patent"), and 8,193,219 (the "'219 Patent").

[61] Unlisted patents can be asserted in infringement suits filed after a generic product has launched, in an effort to obtain damages on prior sales. Celgene did not do so here. It is rare that—outside of the Hatch Waxman Act paragraph IV scheme—a brand company tries to obtain a preliminary injunction to prevent a competitor from launching as such motions for preliminary injunctions impose a very high standard.

frivolous infringement claims for unlisted patents in response to ANDAs for lenalidomide, as further discussed below.

B. Celgene Manipulates the FDA's REMS Program to Block Generic Competition

124. Central to Celgene's multi-faceted and decades-long scheme to unlawfully monopolize the markets for Revlimid was its REMS abuse. Celgene used its REMS distribution programs as a pretext to refuse to sell samples of Revlimid to competitors that were necessary to develop ANDAs even at market (and, thus, presumably profitable) prices. These actions ultimately delayed the introduction of generic Revlimid, despite the best efforts of generic competitors and warnings by the FDA to Celgene that such behavior was unwarranted and unlawful. Celgene's claimed business justifications for its refusals to provide samples were entirely pretextual because it freely provided samples to researchers and marketers not seeking to enter the Revlimid market, but not to competitors, who were.

1. Celgene's REMS Programs for Revlimid and Thalomid is Used to Unlawfully Withhold Lenalidomide for Bioequivalence Testing

125. The REMS distribution programs for Revlimid require healthcare providers and pharmacies to be certified in the RevAssist program, and patients to be enrolled, before they prescribe, dispense, or take the drugs. Prescribers and pharmacists must complete registration forms. Women of childbearing age must take a pregnancy test 24 hours prior to starting a course of Revlimid and at least every four weeks during their course of treatment. Prescribers must provide patients with contraception and emergency contraception counseling with each new prescription. For every new patient, prescribers must submit to Celgene a signed Patient-Physician Agreement Form that identifies the patient's risk category. The prescriber then receives a letter confirming the patients' enrollment, and the patient and prescriber receive an authorization number to be written on the prescription. The pharmacy must verify that each prescription has an authorization number that is valid for seven days. The pharmacy must then call Celgene, obtain a confirmation number, and write this number on the prescription. The

prescription is then filled within 24 hours. No more than a 28-day supply of Revlimid may be dispensed at one time.

126. Celgene abused its REMS program as a pretextual justification for withholding Revlimid samples from generic competitors. It did the same with Thalomid. Among the generic manufacturers that Celgene refused to supply samples were Mylan Pharmaceuticals Inc. ("Mylan") between 2004 and the present; Lannett Company, Inc. ("Lannett") in 2006; Exela Pharma Sciences, LLC ("Exela") in 2006; Dr. Reddy's Laboratories ("Dr. Reddy's") in 2008 and 2009; Watson Laboratories, Inc. ("Watson") in 2009; Teva Pharmaceuticals USA ("Teva") in 2009; and Sandoz Inc. ("Sandoz") in 2012. Celgene also entered into an exclusive supply agreement with a French thalidomide supplier to prevent Barr Laboratories ("Barr") from obtaining that company's thalidomide API,

127. Celgene's improper use of the REMS program as a pretext to refuse to provide samples is contrary to the FDAAA. The FDAAA provides that "no holder of [a REMS-covered drug] shall use any element to assure safe use . . . to block or delay approval of . . . an [ANDA application]."[62]

2. REMS Programs Do Not Apply to Generic Manufacturers Obtaining Bioequivalence Samples

128. Celgene's REMS distribution programs are post-marketing, commercial distribution programs—*i.e.*, they are intended to address only sales to consumers and healthcare organizations dispensing the drug. Celgene's REMS protocols do not discuss or otherwise reach drug manufacturers conducting business with one another in the pre-marketing, drug development phase. Nor do Celgene's REMS protocols discuss or prevent distribution of samples to drug manufacturers.

129. A generic manufacturer's safety protocols are not required to be FDA-approved for the generic manufacturer to purchase samples of a drug subject to a REMS program. Indeed, according to Robert West, former Deputy Director of FDA's Office of Generic Drugs ("OGD"), a

[62] 21 U.S.C. § 355-1(f)(8).

generic manufacturer is not required to submit its protocols to the FDA before commencing bioequivalence studies.[63]

130. Clinical and pre-approval studies are not governed by REMS. In an August 2012 meeting with Celgene, the FDA explained, "Celgene's REMS relates to a marketed situation and not a clinical trial where there is more control regarding administration of the product and the amount given is monitored and very limited."

131. A sample supply of a brand name drug, including the API, is required to manufacture a generic equivalent. The API is used to conduct the required bioequivalence testing that the FDA requires to be included in the generic manufacturer's ANDA.

132. Due to Celgene's REMS program, generic manufacturers were unable to purchase Revlimid samples in the United States through normal wholesale distribution channels. The restricted network that Celgene created forced would-be generic competitors to purchase the drugs directly from Celgene and to provide evidence of the FDA's endorsement of their request. Thus, Celgene improperly utilized its REMS program to thwart generic competition by refusing to sell API samples to generic manufacturers and to block third parties in possession of Revlimid API from doing so as well.

3. Celgene Refuses to Sell API Samples to Mylan

133. Celgene repeatedly refused to sell both Revlimid and Thalomid samples to Mylan.

134. Mylan began developing a generic thalidomide product on September 26, 2003. Shortly thereafter, on October 27, 2003, Mylan requested guidance from OGD on prospective bioequivalence studies. The requested guidance was provided by the OGD within the following year.

135. On December 22, 2003, in order to manufacture its formulation of thalidomide, Mylan requested thalidomide API from two API suppliers: GYMA Laboratories of America, Inc. ("GYMA") and Antibioticos S.A. ("Antibioticos"). By March 11, 2004, Mylan received only a limited supply of thalidomide API from Antibioticos.

[63] Br. in Opp. Summ. J. for Mylan at Ex. P18, *Mylan Pharm. Inc. v. Celgene Corp.*, Case No. 14-cv-2094 (D. N.J. Mar. 20, 2018) (hereinafter "Mylan Opp."); ECF No. 285-15 at 128-29.

136. In September 2004, after Mylan was unable to gain sufficient access to Thalomid samples from traditional API suppliers, the FDA suggested Mylan contact Celgene directly to request the necessary samples, which Mylan did.

137. On October 5, 2004, Mylan attempted to purchase 2,500 Thalomid capsules from Celgene to conduct bioequivalence studies. Celgene failed to respond to the request. Mylan repeated its request on May 3, 2005. By this point, Mylan had already completed safety training sessions for the handling and testing of thalidomide.

138. Celgene finally responded on June 21, 2005. In a letter response, Celgene explained that, pursuant to its S.T.E.P.S. program, Thalomid was not available through normal wholesale channels, and that it was against Celgene's policy to deal with third parties in the sale of Thalomid.

139. In a now unsealed internal email from July 6, 2005, Celgene reported that "Mylan has had difficulty obtaining enough of Celgene's reference product to perform [bioequivalence] studies, so its ANDA submission is expected to be delayed until late in the third quarter of 2005."

140. On September 2, 2005, Mylan once again contacted Celgene directly and sought to purchase 3,360 Thalomid capsules for bioequivalence testing.[64] In its request, Mylan explained that the "FDA had recommended that we contact you directly to request a sample" of Thalomid for bioequivalence testing, and that "obtaining samples through other traditional channels is nearly impossible."

141. On October 20, 2005, Celgene replied to Mylan's request and claimed that it needed additional time to consider the request and "to avoid fetal exposure."

142. By December 2005, Mylan completed its scale-up of its experimental thalidomide batch. Mylan had, by that time, captured two-years' worth of stability data. The only remaining step to submitting its ANDA to FDA was to conduct bioequivalence studies.

[64] Op., *Mylan Pharm. Inc. v. Celgene Corp.*, Case No. 14-cv-2094 (D. N.J. Oct. 3, 2018) (hereinafter "Mylan MSJ Op."), ECF No. 287 at 18.

143. On December 19, 2005, Celgene claimed that it would need the FDA's approval to allow Mylan to purchase samples outside of the S.T.E.P.S. program: "[W]e recommend that you contact [the] FDA's [Division of Special Pathogen and Transplant Products] to discuss the importance of the S.T.E.P.S. program to them." Celgene also claimed that if the FDA then "contacts us in writing and recommends that we violate our S.T.E.P.S. program by providing you with the quantity of THALOMID you request, we will further evaluate your request at that time."[65]

144. Celgene's response was not only contrary to law, but to an internal report created just a couple of years earlier relating to Mylan's safety protocols. In the 2003 report, Celgene conceded that Mylan's patient monitoring system—already in place for another drug it was studying—was robust, comprehensive, and equivalent to the S.T.E.P.S. program. Celgene's internal report also concluded that Mylan's safety protocols "currently have very sophisticated patient monitoring systems for their respective clozapine products."[66] The report further stated that "it can be observed that the clozapine requirements are as comprehensive as the S.T.E.P.S. program."[67]

145. On January 11, 2006, having received continuous push back from Celgene, Mylan requested the FDA's assistance to obtain the necessary Thalomid samples required for bioequivalence testing.[68] In its letter, Mylan proposed protocols to ensure avoidance of fetal exposure.[69]

146. On February 12, 2007, the FDA replied, requesting an investigational new drug application ("IND") or study protocol so that it could "ensure that all appropriate safeguards for a

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[65] *Id.*

[66] Mylan Opp. at Ex. P137, ECF No. 286-1 at 183 (CELM-THOF-000004370).

[67] *Id.*

[68] Mylan MSJ Op. at 18.

[69] *Id.*

clinical investigation with thalidomide are in place" as a substitute for the S.T.E.P.S. program.[70] The FDA made its position on Celgene's delay tactics clear, stating:

> It is FDA's view that certain restrictions are needed to ensure safe use of the drug; however, ***it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product***. The agency believes that such bioequivalence studies can be conducted safely under either an IND or in circumstances that provide alternative assurance of patient safety.
>
> To ensure that the intention of Congress in enacting the generic drug approval provisions in section 505(j) is not frustrated by the terms of the S.T.E.P.S. program, ***FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid (including 200 units for the purpose of conducting bioequivalence (including dissolution)*** testing and 300 units for a limited number of retained samples) when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects.[71]

147. On May 1, 2007, Mylan produced to the FDA its proposed thalidomide safety protocols, which the FDA reviewed, found "acceptable," and so notified Mylan on September 11, 2007.[72]

148. On November 16, 2007, Mylan notified Celgene of the FDA's approval and directive, which directly addressed any purported justification by Celgene for not providing the requested samples. Celgene's senior executives and officers concede that the FDA is the ultimate authority on setting safety standards. Yet Celgene continued to deny Mylan's (and others')

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[70] *Id.*

[71] Letter from Gary Buehler, Office of Generic Drugs, CEDR, FDA to Lannett Co., Inc. (Feb. 12, 2007), *available at* Verified Compl., *Lannett Co., Inc. v. Celgene Corp.*, Case No. 08-cv-3920 (E.D. Pa.), ECF No. 1 at 21 (emphasis added).

[72] Mylan MSJ Op. at 19.

requests for drug samples for bioequivalence testing and used pretextual and obviously flawed safety concerns as its chief justification for doing so.[73]

149. Celgene repeated these same dilatory tactics when Mylan requested samples of Revlimid, which Mylan began developing as a generic in or about June 2007. According to internal emails from September 2007, Mylan planned to file its ANDA for generic Revlimid on December 27, 2009, and was actively sourcing raw materials. Mylan reportedly planned to design around the formulation patent.

150. In early 2009, Mylan attempted to purchase lenalidomide samples to manufacture a generic version of Revlimid, buts its efforts were thwarted by Celgene. Celgene did not even attempt to hide its attempts to block generic competition, including to the FTC—Celgene reported to the FTC that "Celgene ha[d] decided not to sell REVLIMID® at the present time to manufacturers."[74]

151. Only after being pressed by the FTC in 2012 did Celgene indicate a willingness to sell Thalomid and Revlimid to generic manufacturers for bioequivalence testing."[75] But Celgene's representations to the FTC did not reflect reality, as Celgene was not willing and, more to the point, was still refusing to sell the necessary samples to generic manufacturers. Remarkably, at the same time Celgene was indicating to the FTC its willingness to sell both Thalomid and Revlimid to would-be generic entrants, Celgene was taking an entirely different position with the FDA. On August 14, 2012, in correspondence with the FDA, Celgene indicated it had no obligation to sell bioequivalence samples to a generic manufacturer and threatened to continue to withhold bioequivalence samples of Revlimid from generic manufactures "unless and

[73] *Id.* On April 21, 2000, the FDA sent Celgene a "Warning Letter" stating that "Celgene has engaged in promotional activities that state or suggest that Thalomid is safe and effective for use in treating multiple myeloma." With no generics on the horizon, Celgene was willing to play fast and loose with the safe distribution of Thalomid so long as it ensured increased utilization and increased profits.

[74] Mylan Opp. at Ex. P201, ECF No. 286-4 at 97 (CELM-COUO-000010496).

[75] *Id.*

until the FTC and the State of Connecticut Attorney General agree[d] to close their investigation(s)."[76]

152. On May 1, 2013, Mylan once again requested bioequivalence samples of Revlimid from Celgene and advised that Mylan's safety protocols had been submitted to the FDA.[77]

153. As it did with Mylan for Thalomid samples, Celgene imposed numerous additional and unnecessary hurdles for Mylan to obtain Revlimid samples. On May 14, 2013, Celgene told Mylan that it would provide Revlimid samples for bioequivalence testing *only after* Mylan signed an indemnification agreement, entered into a "Supply Agreement," and provided Celgene with "nine categories of information" including "written confirmation the FDA will allow Celgene to sell the requested amount of Revlimid . . . to Mylan."[78]

154. On March 11, 2014, Mylan provided Celgene with a July 29, 2013 letter from the FDA confirming that Mylan's Revlimid safety protocols had been approved.[79] Celgene responded on March 20, 2014 that it would sell samples only upon its "satisfactory review of the documents and information" it previously requested and execution of a Supply Agreement.[80]

155. Exasperated with Celgene's tactics, Mylan filed suit against Celgene shortly thereafter on April 3, 2014, asserting violations under federal and state antitrust laws for its anticompetitive tactics to maintain monopoly power in the market for Thalomid and Revlimid.[81]

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[76] *Id.* at Ex. P17, ECF No. 285-15 at 121 (CELMN-FREJ-000104033). Both the FTC and the State of Connecticut had active investigations during this time seeking both documents and information relating to Celgene's refusal to provide Thalomid and Revlimid to generic manufacturers. *See* Letter from Celgene Corp. to Mr. Jim Rosenberg, Senior Assistant Chief Accountant, SEC, at 4 (May 5, 2016), https://www.sec.gov/Archives/edgar/data/816284/000110465916118387/filename1.htm.

[77] *Id.* at 19-20.

[78] *Id.* at 20.

[79] *Id.*

[80] *Id.* at 31.

[81] Compl., *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094 (D. N.J. Apr. 3, 2014), ECF No. 1.

156. Subsequently, in a May 19, 2014 letter from the FDA to Celgene, the FDA further confirmed with Celgene that it "will not consider it a violation of the REMS for Celgene to provide to Mylan (or its agent) a quantity of Revlimid sufficient to allow Mylan to perform the testing to support its [ANDA]."[82] The FDA also warned Celgene that federal law prohibits branded manufacturers from "using [REMS' elements] to block or delay approval of an ANDA" and that it "expect[ed] Celgene to provide Mylan with a sufficient quantity of REVLIMID to conduct necessary testing, but in any event no less than 500 capsules of each strength (2.5mg, 5mg, 10mg, 15mg and 25mg)."[83]

157. In flagrant disregard for the FDA's warning, Celgene continued to refuse to provide Mylan with the requested Revlimid samples.

4. Celgene Boasts About Successfully Delaying Generic Competition by Blocking Bioequivalence Testing

158. Despite Mylan agreeing to jump through the various hoops set out by Celgene and provide *all* the information being requested in order to acquire Thalomid and Revlimid samples, including proof of liability insurance covering any instances relating to the drug's misuse and an extensively negotiated indemnity agreement, which agreed to hold Celgene harmless in the event of any injury or misuse, it is now clear that Celgene never actually intended to provide the requested samples to Mylan.

159. On August 1, 2008, Celgene indicated in a written response to Mylan that it was "carefully reviewing" Mylan's documentation regarding Thalomid samples.[84] It was later revealed through the testimony of Celgene's then-Regulatory and Compliance Counsel that as of March 4, 2011—more than six years after Mylan's initial request for API samples—no "business people" at Celgene had reviewed *any* of Mylan's documentation.[85]

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[82] Mylan MSJ Op. at 31.

[83] *Id.*

[84] *Id.* at 33.

[85] *Id.*

160. Notwithstanding this now known fact, Celgene continued to double-down on its false narrative, including in interrogatory responses produced in connection with a later FTC investigation. In those verified interrogatory responses, Celgene reported that its two CEOs obtained legal advice from Celgene's Deputy General Counsel and then-Regulatory and Compliance Counsel on its dealings with, and responses to, pharmaceutical companies seeking to purchase Revlimid and Thalomid samples for bioequivalence testing.[86] Both CEOs, however, later testified in a separate litigation that they were not consulted, nor did they consult others, including legal counsel, about Celgene's decision to deny samples to prospective ANDA applicants.

161. One Celgene CEO testified at deposition that he "did not have any input into Celgene's information requests … , did not know for sure who had provided input, and had never seen Mylan's [response] to Celgene's requests[.]"[87] He additionally testified that he "could not recall reviewing 'a single response from a generic company' to Celgene's information requests, or sitting in any meeting with Celgene's legal, regulatory, or drug safety departments" relating to Thalomid or Revlimid samples.[88] The other Celgene CEO similarly testified that he had "no personal knowledge of whether anyone at Celgene "actually reviewed the protocols submitted by various generic companies over time."[89]

162. Nearly one year after Celgene falsely reported to Mylan that it was reviewing its documentation for acquiring Thalomid samples, on June 24, 2009, Celgene wrote to Mylan indicating there were still "outstanding issues" with the information Mylan provided and requested nine additional categories of information.[90] But the later release of an internal Celgene

[86] *Id.* at 34.

[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] Celgene would later request the same amount of information from Mylan in response to Mylan's repeated requests for Revlimid samples.

email dated May 22, 2009 further confirmed Celgene's true motivations during this time. The email identified a project titled "Thalidomide Multiple Myeloma" and included the following summary:

> A generic thalidomide application was successfully delayed until at least June '09 in the USA. Celgene may further extend its exclusivity in the USA by using bioequivalence as a generic defense strategy….[91]

The email confirms that Celgene was never truly concerned with the safe distribution of Thalomid (and, later, Revlimid), but rather used safety as a pretextual justification to prevent generic competition.

163. Indeed, this Court has already held, based on these facts, that one could reasonably infer "that Celgene had no objectively legitimate business justification for not selling Mylan samples of Thalomid® or Revlimid® samples after FDA approval of Mylan's study protocols."[92]

164. In short, Celgene had absolutely no legal justification or other legitimate basis for refusing to sell Mylan, a potential generic competitor, the samples it needed for bioequivalence testing. Celgene's only purpose was to preserve its monopoly by thwarting generic competition.

5. Celgene Refuses to Change its Anticompetitive Practices, Even in the Face of Government Scrutiny

165. Celgene's refusal to supply Mylan and other generic competitors with bioequivalence samples has prompted government investigations and persistent condemnation but has been unable to halt Celgene's (and later, BMS's) anticompetitive behavior.

166. For example, the FDA specifically included Revlimid and Thalomid on a publicly published list of brand name drugs that had been the target of complaints because their brand

[91] Mylan Opp. at Ex. P205, ECF No. 286-4 at 104, n. 1 (referring to CELM-HUG-000024508).

[92] Mylan MSJ Op. at 35. Indeed, Celgene has historically overstated the legal "basis on which liability" could be extended to a brand name manufacturer to deny the provision of samples to generic competitors. Order on Celgene's Mot. Dismiss, *In re Thalomid and Revlimid Antitrust Litig.*, No. 14-cv-6997 (D. N.J. Oct. 29, 2015), ECF No. 68 at 32; *see id.* ("The possibility that Celgene could be liable for a generic drug's harm is therefore not a legitimate justification that would support its refusal to supply generic manufacturers with samples of Thalomid and Revlimid.").

manufacturer is and/or had been denying access to bioequivalence samples when generic companies seek to buy them.[93]

167. The Connecticut Attorney General's office also separately initiated an investigation into Celgene's alleged REMS abuse relating to both Revlimid and Thalomid, and wrote in January 2013 that Celgene's responses to its REMS abuse inquiry "ha[ve] raised serious concerns" that "notwithstanding its claims to the contrary, Celgene is not truly willing to sell Revlimid samples in a manner that would allow the [bioequivalence] testing necessary for a competitor to submit an ANDA" and "Celgene's current actions raise the specter that the discussions have been nothing but an artifice to continue to allow Celgene to delay the development of a generic alternative to Revlimid."[94]

168. In addition, in August 2012, as mentioned above, the FTC investigated and served interrogatories on Celgene regarding its REMS abuse, including questions about what additional information Celgene needed to authorize the sale of Revlimid to generic manufacturers. The FTC specifically stated: "in the interest of advancing our discussions and trying to reach a prompt resolution with you, we propose the FTC and Celgene meet together with FDA . . . to discuss what Celgene thinks it needs from [the] FDA in order to be able to make prompt sales to generic firms."[95]

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[93] FDA received numerous access inquiries for Celgene's Thalomid, Revlimid, and Pomalyst (pomalidomide). The published list reveals that the FDA received ten inquiries relating to Thalomid samples, thirteen inquiries relating to Revlimid samples, and eight inquiries relating to Pomalyst samples. The FDA issued at least four warning letters for Revlimid, including on July 21, 2012, May 19, 2014, February 22, 2017, and August 15, 2017. And the FDA issued at least two warning letters for Thalomid on December 12, 2007, and January 17, 2008.

[94] *See e.g.,* Statement of Markus H. Meier, Acting Dir., Bureau of Competition, FTC, before U.S. House of Rep., at 7 (Jul. 27, 2017), https://www.ftc.gov/system/files/documents/public_statements/1234663/p859900_commission_testimony_re_at_concerns_and_the_fda_approval_process_house_7-27-17.pdf ("Despite clear guidance from both Congress and [the] FDA that drug firms should not use REMS programs to block or delay generic or biosimilar competition, complaints about abuse of the regulatory process persist . . . One study estimates that Americans have lost $5.4 billion in annual savings due to delays in accessing drug samples caused by REMS misuse and other non-FDA mandated restricted distribution programs.").

[95] Mylan Opp. at Ex. P27, ECF No. 285-16 at 198 (CELMN-PASM-000002338).

169. In February 2013, the FTC's Bureau of Competition ("BOC") followed up on the FTC's earlier inquiry to Celgene. In a letter to Celgene's counsel, the BOC stated "that there is a lot of concern here—at both the Bureau and Commission levels—about the time it has taken for your client to [redacted] of Revlimid capsules" for bioequivalence testing and advising that "the Commission's patience is wearing thin. We have reached a point where the staff may be instructed in the very near future to commence litigation."[96]

170. The FTC would later write an amicus brief in support of Mylan's antitrust suit against Celgene, and later began to regularly testify before Congress to raise the alarm regarding REMS abuse by Celgene and others.[97] The FTC ultimately submitted statements to the Department of Health and Human Services ("DHHS") and urged its action.[98]

6. Celgene Refuses to Sell API Samples to Other Generic Manufacturers

171. Mylan was not the only would-be generic entrant blocked by Celgene's anticompetitive tactics. Indeed, numerous other generic manufacturers attempted to obtain sufficient quantities of lenalidomide from Celgene but were consistently denied access and made to jump through numerous unnecessary and unjustified hoops as part of Celgene's anticompetitive scheme to delay generic competition.

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[96] Mylan Opp., ECF No. 285 at 16.

[97] *Antitrust Concerns and FDA Approval Process*, Prepared Statement Markus H. Heier, Bureau of Comp., FTC before the Subcomm. on Regulatory Reform, Comp. and Antitrust Law, Judiciary Comm., United States House of Representatives, Washington, D.C. (July 27, 2017), https://www.ftc.gov/public-statements/2017/07/prepared-statement-federal-trade-commission-antitrust-concerns-fda; *Oversight of the Enforcement of the Antitrust Laws*, Prepared Statement of the FTC before the Subcomm. on Antitrust, Comp. Policy and Consumers Rights, Judiciary Comm., U.S. Senate (Oct. 3, 2018).

[98] *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, Statement of the FTC to the U.S. Department of Health and Human Services (July 16, 2018), available at http://www.ftc.gov/system/files/documents/advocacy_ documents/statement-federal-trade-commission-department-health-humanservices-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs.pdf. ("[b]y improperly blocking the product developer from obtaining samples, the branded manufacturer can potentially delay or indefinitely block generic or biosimilar competition to its product, thereby reducing the competition that Congress specifically sought to facilitate via the Hatch-Waxman Act . . . .").

a) Celgene Refuses to Provide Thalomid Samples to Exela

172. On May 31, 2006, Exela Pharma Sciences, LLC ("Exela") contacted Celgene and informed it of Exela's intention to file an ANDA for Thalomid. Exela stated it was having difficulty obtaining samples of this drug from other channels, much like the other generic manufacturers who had contacted Celgene. Exela requested a proposal for purchase within 10 days.

173. On June 27, 2006 Exela sent a follow-up letter to Celgene again requesting to purchase Thalomid samples. In its letter, Exela noted the 10-day window for a purchase proposal had lapsed despite being received the day after it was sent.

174. On September 11, 2007, the FDA's OGD wrote to Exela that its "proposed bioequivalence study protocol comparing Thalidomide Capsules, 200 mg to [Thalomid] is acceptable . . . ."

175. On December 11, 2007, FDA OGD Director Gary J. Buehler sent a letter to Celgene's internal regulatory counsel, Kerry Rothschild stating that "FDA has reviewed the bioequivalence protocol submitted . . . on behalf of Exela and has received sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects and has determined that Celgene may provide Exela with 500 units of Thalomid as indicated in FDA's letter to you dated February 8, 2007 for the purposes of conducting an in vivo bioequivalence study and in vitro dissolution testing."

176. Over a year later, on January 8, 2008, counsel for Celgene contacted counsel for Exela regarding the Thalomid purchase request.

177. In a response almost identical to ones given to other generic manufacturers, Celgene stated it did not believe it was obligated to turn over any samples. However, it continued, if Exela were to comply with a list of 10 demands for information, including, for example, proof of liability insurance and a history of product loss due to improper handling or tracking, Celgene would then "reconsider" its denial. Upon information and belief, Celgene never provided Exela with the requested samples of Thalomid.

b) Celgene Refuses to Provide Thalomid Samples to Lannett

178. On September 6, 2006, Lannett Company, Inc. ("Lannett") wrote a letter to FDA requesting bioequivalence recommendations regarding thalidomide capsules.

179. FDA OGD responded to Lannett's letter on February 12, 2007. FDA OGD stated that "it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product."

180. FDA OGD commented that, to ensure Congress' intentions in enacting the Generic Drug Approval Provisions in Section 505(i) are carried out, "FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid . . . for the purpose of conducting bioequivalence testing."

181. On February 8, 2007, FDA notified Celgene that "a study protocol would be reviewed by FDA to ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place" if a proposed generic manufacturer wished to conduct BE studies. FDA explained that it would "exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid for the purpose of conducting bioequivalence testing, when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the [BE] study will be conducted in such a manner as to ensure the safety of the subjects."

182. FDA's letter also requested Celgene submit a supplement to its own Thalomid NDA to the same effect. Celgene failed to submit this supplement, evidencing its own disregard for safety (and the FDA).

183. Nevertheless, Celgene's then-regulatory counsel Kerry Rothschild testified that FDA's February 8, 2007 letter did not fully assuage Celgene's worry that a fetal exposure and birth of a baby with thalidomide-recognizable defects would have consequences to the value of

Celgene's business.[99] Celgene Chief Executive Officer, Mark Alles, testified in 2016 that of the small number of fetal exposures to Thalomid between its development and 2016, the exposures "had minimal impact on the business."[100]

184. In a July 26, 2007 letter to Celgene, Arthur P. Bedrosian, President and CEO of Lannett, wrote:

> In order to complete our bio-study, FDA has instructed us to purchase 250 Thalomid 200 MG Capsules from you. We kindly request information as to how to best carry out this transaction. We will be happy to supply a purchase order once you provide us with the total product cost. Submitted with this document, you will find the appropriate licenses necessary for us to purchase the product from you. We kindly ask that you inform us of any additional information you will need to complete this transaction.

185. Upon information and belief, in September 2007, Lannett faxed to Celgene's Darnell Ragland, Manager, Customer Care of Celgene, a requested copy of the February 12, 2007 FDA letter, which authorized Lannett to acquire Thalomid supplies from Celgene.

186. Celgene continued to refuse Lannett's request. Celgene even went as far as actively screening any communication from Lannett directed towards Celgene regarding requests for samples of Thalomid.

187. In a September 28, 2007 internal email (only made publicly available in redacted form in 2018), a Celgene training alert ordered employees "**DO NOT PROCESS THE ORDER**" (emphasis in original) if a generic company calls or writes requesting to order Thalomid. Instead, the call center employees were directed to log the call, advise that a management team member would return the call, and to never transfer the call to someone higher up.

188. Employees were further instructed to forward any similar correspondence via fax to one of their supervisors.

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[99] Mylan Opp. at Mylan's Resp. to Celgene's Sep. Statement of Facts, ¶¶ 157, 197, ECF No. 285-1 at 107, 126.

[100] Mylan Opp. at Ex. P115, ECF No. 286 at 185-186.

189. Then, on October 18, 2007, Lannett wrote a letter to Mr. Ragland reiterating Lannett's request so that it could conduct BE testing needed to obtain approval to market its generic thalidomide.

190. On January 8, 2008, Celgene advised Lannett that it would not provide samples of Thalomid to Lannett. Rather, Celgene requested Lannett produce voluminous and unnecessary documentation in order for Celgene to "reconsider" the request.

191. On January 14, 2008, Lannett filed a complaint against Celgene seeking, among other things, mandatory injunctive relief requiring Celgene to provide samples of Thalomid as contemplated by the February 12, 2007 FDA letter.[101] The case was dismissed without prejudice.

192. Lannett then provided almost all of the information that Celgene requested except its highly confidential FDA Form 483 inspection reports, which relate to the routine inspection of manufacturing facilities, given that the Thalomid samples Lannett requested would not be used for manufacturing, but rather for BE studies that it would perform overseas.

193. Lannett submitted its proposed study for FDA review and received approval on August 11, 2008.

194. Lannett refiled its Complaint on August 15, 2008 alleging violations of the Sherman Act and seeking injunctive relief. Celgene filed its motion to dismiss on November 4, 2008. Celgene sought, in the alternative, a stay of the action pending resolution of its citizen petition. Celgene argued that it had no obligation to sell Lannett samples because it believed that there should be no generic competition for Thalidomide in the United States at all.[102]

195. While the motion to dismiss was pending, the parties reached a settlement agreement for Celgene to provide Lannett with samples in July 2009. When Celgene continued to decline to supply the samples, litigation renewed, with Celgene renewing its arguments that there should be no generic competition for Thalidomide.

[101] *Lannett Company, Inc. v. Celgene Corp.,* No. 08-cv-0233. (E.D. Pa.).

[102] Motion to Dismiss, *Lannett Co., Inc. v. Celgene Corp*., No. 08-cv-3920, ECF No. 12 (E.D. Pa. Nov. 4, 2008).

196. Celgene's motion to dismiss or stay the proceeding was summarily denied without prejudice on May 13, 2010,[103] and again summarily denied on March 31, 2011.[104]

197. A week before summary judgment briefs were due, the court held a settlement conference on December 1, 2011, at which Celgene reached a confidential settlement with Lannett and the action was dismissed.

198. In its 2012 Annual Report, Lannett stated that "a sizable portion of our fiscal 2013 R&D budget is earmarked for two large market opportunity projects, C-Topical and Thalidomide." Its 2013 Annual Report stated that Lannett "successfully passed critical milestones for submitting a product application for Thalidomide." As discussed below, Lannett eventually filed a thalidomide ANDA in late 2014.

199. Upon information and belief, the settlement between Celgene and Lannett may have contained anticompetitive terms, such as a promise to delay submission of the ANDA.

200. The anticompetitive effect of Celgene's conduct was to delay Lannett's ANDA. Though Lannett began requesting Thalomid samples in 2006, it was unable to obtain such samples due to Celgene's delay until at least after December 2011 and did not file its ANDA until 2014, at which time Celgene filed a sham patent litigation, discussed below, all to delay Lannett's thalidomide product. Generic thalidomide—a drug that has been around since the 1950s—was not approved by the FDA until April 27, 2023. Not surprisingly, the generic manufacturer of generic thalidomide is Defendant Natco.

c) Celgene Refuses to Provide Revlimid Samples to Defendant Dr. Reddy's

201. Dr. Reddy's requested samples of Revlimid from Celgene to perform BE testing in August 2008. Celgene did not reply to this request.[105]

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[103] Order, Lannett Co., Inc. v. Celgene Corp., No. 08-cv-3920, ECF No. 27 (E.D. Pa. May 13, 2010).

[104] Order, No. 08-cv-3920, ECF No. 42 (E.D. Pa. Mar. 31, 2011) (denying renewed motion to dismiss).

[105] U.S. Food & Drug Admin., Dr. Reddy's Citizen Petition Docket No. 2009-P-0266, at 8 (Jun. 10, 2009), https://www.regulations.gov/document/FDA-2009-P-0266-0001.

202. Dr. Reddy's repeated its request in December 2008. Celgene offered a single sentence reply in January 2009: "Celgene has no obligation to supply Dr. Reddy's with Revlimid and declines to do so."[106]

203. In its request to Celgene, Dr. Reddy's assured Celgene any testing it performed would comply with FDA guidelines, using methods similar to Celgene's REMS program known as RevAssist to insure proper handling of the subject drugs.[107]

204. Dr. Reddy's filed a citizen petition with FDA in June 2009, alleging that Celgene was refusing to provide samples to a generic drug manufacturer to perform BE testing.[108]

205. Celgene once again premised its refusal on its REMS program, despite FDA's previous guidance.

206. On or about July 12, 206, Dr. Reddy's filed an ANDA for a generic lenalidomide product in the 2.5, 5, 10, 15, 20, and 25 mg strengths. Dr. Reddy's was the first to file an ANDA for 2.5 and 20 mg strength lenalidomide. As discussed below, Celgene then sued Dr. Reddy's claiming patent infringement.

d) Celgene Refuses to Provide Revlimid Samples to Defendant Teva

207. Teva requested a total of 5,000 Revlimid Capsules in 5, 10, 15, and 25 mg dosages from Celgene to perform bioequivalence testing in March 2009.[109]

208. In its letter to Celgene, Teva stated that its ". . . procedures for conducting any required testing involving lenalidomide and the Revlimid drug product provided by Celgene Corporation will fully comply with FDA requirements. Teva's controls with respect to lenalidomide will be comparable to the RevAssist program."

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[106] *Id.*

[107] *Id.*

[108] *Id.* at 1.

[109] At this point in time, Teva and Watson were separate companies. Teva acquired Watson as part of its acquisition of Actavis Generics from Allergan plc in 2015.

209. In April of 2009, Celgene responded to Teva's request, and in a one sentence reply, stated "[t]his letter is to inform you that your request for 5,000 capsules of REVLIMID (lenalidomide) in varying strengths is declined."

210. Celgene's refusal to provide Teva with samples of Revlimid follows a similar course of conduct as with refusals to other generic pharmaceutical companies.

e) Celgene Refuses to Provide Thalomid and Revlimid Samples to Watson

211. In June of 2009, much like the other generic manufacturers described above, Watson contacted Celgene to acquire samples of Revlimid and Thalomid for bioequivalence testing.[110]

212. In its request, Watson assured Celgene the process by which it would handle the samples of these drugs would fully comply with a restricted distribution system similar to RevAssist.

213. Furthermore, Watson assured Celgene that FDA guidelines would be followed, and no drug would be distributed in violation of these guidelines, which would have been unlikely to happen given Watson's vast experience and expertise in the generic drug manufacturing market.

214. In July 2009, despite Watson's assurances that the requested samples would be handled in a safe, effective, and FDA-compliant manner, Celgene responded with a list of ten pieces of evidence and documentation Watson would need to provide before Celgene would consider Watson's request. Celgene indicated it would respond to Watson's request for Revlimid in a separate letter.

215. Tellingly, Celgene did not say satisfying these ten requirements would facilitate a prompt sale of the samples, merely that at that time Celgene would "consider" it.

[110] At this point in time, Teva and Watson were still separate companies. Watson would later merge with Actavis Group in November 2012. Actavis would then merge with Allergan plc in 2015, though the Actavis Generics were acquired by Teva by this point in time.

216. Upon information and belief, like the generic manufacturers before and after, Watson was unable to obtain the samples of Revlimid and Thalomid it requested, with no logical reason provided.

f) Celgene Refuses to Provide Thalomid and Revlimid Samples to Sandoz

217. In May of 2012, much like the other generic manufacturers described above, Sandoz Inc. ("Sandoz") contacted Celgene attempting to acquire samples of Revlimid and Thalomid for BE testing.

218. In response, Celgene refused to provide the samples, and instead listed nine prerequisites Sandoz had to satisfy before it would consider selling the requested samples.

219. These prerequisites included that Sandoz provide "Proof of liability insurance sufficient to cover events associated with thalidomide and lenalidomide," "[p]olicies for biohazard handling, disaster recovery plans as well as the storage and use of teratogenic products," and "[w]ritten confirmation that an IND is in effect or a study protocol . . . has been approved by FDA."

220. Like its correspondence with other generic manufacturers wishing to obtain drug samples, Celgene referenced the REMS procedures as a reason it could not immediately supply Sandoz with samples, despite FDA approval of Sandoz's procedures.

221. Upon information and belief, like the generic manufacturers before it, Sandoz was unable to obtain the samples of Revlimid and Thalomid it requested.

7. Celgene Uses REMS Programs as a Blunt Anticompetitive Tool

222. While Celgene claimed that safety concerns prevented it from supplying any potential ANDA sponsor with the necessary and required samples of Revlimid and/or Thalomid, it authorized its competitive intelligence firm, GBMC, to purchase, handle, and transfer thalidomide even though it had no safety training.

223. In 2003, Celgene authorized GBMC to purchase thalidomide API from a European supplier, Alan Pharmaceuticals. In fact, Celgene authorized GBMC to use undercover purchases to obtain samples of thalidomide API from various API suppliers. In an undated letter, GBMC

detailed the sequence of events it used to acquire thalidomide samples outside the normal chains of distribution to satisfy Celgene's request. This sequence included falsifying prescriber names and permitting GBMC (a non-pharmaceutical company without any experience handling teratogenic drug products) to handle thalidomide samples, all without a formal tracking mechanism. Celgene's Senior Director of Market Research testified in a previous litigation that he did not notify Celgene's legal department of these undercover purchases, that Celgene did not do background checks on individuals that would be handling the drug product, and that he could not recall whether the purchased product was in its proper packaging when Celgene received it, or who at Celgene received it.

224. These Celgene authorized transactions did not comport with any safety protocol whatsoever.

225. Celgene also willingly and frequently provided access to Revlimid and Thalomid to non-competitor research organizations for the purpose of conducting clinical studies. It provided access to such organizations outside the REMS process and without FDA guidance or approval for the safe handling of the drug products.

226. Celgene provided Revlimid for at least 3,600 different research and investigational studies, and Thalomid for over 100 investigator-initiated trials ("IIT") without requiring REMs compliance.[111] For example, Celgene provided Revlimid and Thalomid to the Johns Hopkins School of Medicine for clinical trials and provided Revlimid to Intergroupe Francophone du Myelome, University Hospital of Toulouse, and Groupe Francophone Des Myelodysplasies, as well as the National Cancer Institute, Eastern Cooperative Oncology Group, Plaintiff Mayo Clinic, and MD Anderson Cancer Center in Houston, TX.

227. An IIT process is initiated when an investigator submits a Letter of Intent ("LOI") outlining a proposal. The brand company then reviews the proposal. Here, Celgene testified that it tried not to review the full protocol, but rather would typically review a simplified synopsis, along with the nature of the request, the budget, and the amount of drug requested. Celgene typically

[111] IITs are clinical studies initiated and managed by non-pharmaceutical company researchers, such as individual investigators, institutions, collaborative study groups, cohorts or physicians.

adjudicated such requests within two months. Its review did not require in-house counsel assistance. Celgene has never denied an IIT proposal due to fetal exposure safety concerns.

228. After approving an IIT proposal, Celgene works with the investigator to draft a study protocol and consent form to be submitted to FDA for approval. In this specific context, Celgene admitted that FDA's approval gives Celgene confidence in the safety of the trial. Celgene then supplies Revlimid or Thalomid to the investigator to initiate the study.

229. As part of its scheme to monopolize the market for Revlimid, Celgene not only refused to sell samples to its competitors, but also executed exclusive contracts with ingredient suppliers designed to delay competitors from obtaining the necessary resources to file an ANDA. As these suppliers could produce more API than Celgene required, the exclusivity provisions had no business justification and were executed entirely to deny competitors access to API, thereby foreclosing generic entry into the Revlimid market.

230. Celgene's refusal to provide samples of Thalomid and Revlimid to generic manufacturers and execution of an exclusive API supply contract were driven by the same intent—to prevent the entry of generic versions of Thalomid and Revlimid into the market, which would result in the erosion of Celgene's profits. As part and parcel of accomplishing this, Celgene not only refused to supply generic manufacturers with API, but Celgene legally restrained anyone else from doing so as well. In other words, Celgene utilized its REMS program as a pretext to refuse to deal with generic manufacturers and it used exclusive supply contracts to ensure anyone else would refuse to deal as well.

8. Celgene's Anticompetitive and Dilatory Conduct Effectively Delays Generic Competition for Years

231. In prior litigation before this Court, Mylan estimated that had Celgene provided it with Thalomid samples in 2006, it could have ultimately entered the thalidomide market in the third quarter of 2010.[112] As of the date of this Complaint, more than 13 years later, there is *still* no generic competition for Thalomid.

[112] Mylan's expert, Mr. Fetterman, opined "[i]f Celgene had provided brand samples to Mylan and cooperated in developing a shared REMS Program for thalidomide, the SS REMS

232. Similarly, generic manufacturers requested bioequivalence samples of Revlimid from Celgene as early as August 2008, and yet, no generic Revlimid was available until March 2022, a delay of 14 years. And, as more fully described below, the generic Revlimid that became available in March 2022 was constrained by severe restrictions on competition orchestrated by Celgene (and later, BMS).

233. The inability of generic drug manufacturers to bring versions of Revlimid and Thalomid to market was not due to internal issues or manufacturing defects; the only barrier to entry in the market was Celgene's anticompetitive conduct.[113]

C. Celgene Induced API Suppliers into Anticompetitive Exclusive Contracts to Prevent Competing Generic Manufacturers from Acquiring Needed API for Bioequivalence Testing

234. As part of its multi-faceted and decades long scheme to unlawfully monopolize the markets for Revlimid and Thalomid, Celgene not only refused to sell samples to would-be generic competitors, but it also executed exclusive contracts with ingredient suppliers designed to delay competitors from obtaining the needed resources to file an ANDA. As Celgene could not exhaust API supply from these suppliers, the exclusivity provisions had no business justification and were executed entirely to deny competitors access to much needed API, thereby delaying and potentially foreclosing generic entry into the Revlimid and Thalomid markets.

235. One such example of Celgene's anticompetitive efforts to delay generic competition concerns Barr Pharmaceuticals, Inc. ("Barr"), a manufacturer seeking to enter the generic market for Thalomid. Celgene did everything it could to block Barr's ANDA, including preventing Barr from obtaining API supply from Seratec S.A.R.L. ("Seratec"), a French supplier.

236. After the FDA approved Celgene's Thalomid, Barr sought to develop a generic version of thalidomide. In order to secure approval of an ANDA, a proposed generic manufacturer must designate the API manufacturer in the ANDA. The ANDA applicant must

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development and FDA approval likely would have taken 18 to 24 months. Furthermore, this estimate may be conservative, as an alternative parallel agreement to sign onto the S.T.E.P.S. program would have taken even less time, possibl[y] as few as 12 months." Mylan Opp. at Ex. P142, ECF No. 286-2 at 33.

[113] *See* Mylan Opp. at Ex. P71, ECF No. 285-21 at 97-108 (report of Dr. Paul J. Jarosz, Ph.D.).

submit a Drug Master File ("DMF") from the API supplier to the FDA, which is evaluated with the ANDA.

237. In or around 2004, Barr succeeded in procuring thalidomide API from Seratec to develop a generic version of Thalomid by September 2005. Barr submitted its ANDA to the FDA and was waiting to receive a DMF letter from Seratec.

238. Barr's ANDA proposed a skinny label, only seeking approval for Thalomid as a treatment for ENL, and not MM.

239. While Barr and Seratec were in the process of finalizing negotiations, Celgene and Seratec entered into an exclusive supply agreement for thalidomide. Celgene demanded exclusivity from Seratec specifically to interfere with Barr's ability to market generic Thalomid.

240. Inducing this exclusivity agreement was a nakedly anticompetitive action undertaken by Celgene to ultimately delay and exclude Barr from entering the market for Thalomid. Indeed, there are no other potential justifications of Celgene's conduct. Celgene had a separate API supplier that independently was filling its own API supply needs and had sufficient supply to meet its projected growth requirements. And Seratec, itself, had sufficient resources to meet all of Celgene's needs without exhausting supply, leaving Seratec capable of supplying Barr but for the exclusivity provision.

241. As a result of Celgene's anticompetitive conduct, Seratec would not supply Barr with its thalidomide API and the FDA did not accept Barr's ANDA due to deficiencies in providing a DMF from Seratec.

242. Consequently, Barr was forced to find a different thalidomide supplier and repeat testing, causing it great expense and delay in launching generic thalidomide.

243. On February 27, 2006, GBMC (Celgene's competitive intelligence firm) provided an update to Celgene, reporting that Barr had completed its bioequivalence testing and was planning on filing a thalidomide ANDA in the second quarter of 2006 using API from one of two suppliers, either Antibioticos in Italy or Shilpa in India. GBMC explained "[t]hese companies were being used to replace the Seratec API that Barr originally was using for its ANDA."

244. On September 22, 2006, after securing a new supplier and performing new bioequivalence studies and validation testing, Barr submitted its thalidomide ANDA. The ANDA showed that Barr's generic product was bioequivalent to Celgene's Thalomid. On December 4, 2006, the FDA accepted Barr's thalidomide ANDA for filing.

245. True to form, Celgene subsequently initiated a patent infringement lawsuit against Barr for its thalidomide ANDA which, as discussed in more detail below, triggered an automatic 30-month stay of the FDA's approval of Barr's ANDA.

246. GBMC predicted that Barr could be expected to receive FDA approval of its thalidomide ANDA in the first quarter of 2009.

247. A May 2009 internal email released later in connection with other litigation reveals that Celgene executives during this time specifically discussed Barr's attempt to market generic thalidomide in the USA.[114] Meeting minutes contained in the email once again confirm Celgene's pattern of abuse, attempting to use bioequivalence testing as a "generic defense strategy":

> Dianne Azzarello Regulatory Canada discussed possible ways to defend Thalidomide against generic infiltration in the USA. From her experience in working with generic drug providers she is of the opinion that [Celgene was] able to ***use bioequivalence as generic defense strategy***. The team supports this notion.[115]

248. The minutes also reflect discussions about Celgene paying for research and publishing research papers that supported the conclusion that generic manufacturers' version of Thalomid were not bioequivalent. Specifically:

> Diane Azzarello and Henry Lau are working with Dr. Iain McGilveray who will publish a paper providing evidence that many other formulations of thalidomide available are not bio equivalent to Celgene's Thalomid. We may also include our simple formulation and its chemical properties as rationale. Funding for this publication is estimated to be $40k-$60k.[116]

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[114] Celgene's Resp. ISO Mot. Summ. J. in *Mylan Pharm., Inc. v. Celgene Corp.*, No. 14-cv-2094, ECF No. 284-4 at 70-71 (CELM-BOCT-000032393-94).

[115] *Id.* (emphasis added).

[116] *Id.* at 71.

249. These internal discussions further evidence Celgene's bad faith strategies to foreclose generic entry into the markets for Thalomid and later, Revlimid.

250. Traditionally, API manufacturers routinely supplied generic manufacturers with the APIs necessary for bioequivalence testing for other drugs. Celgene changed that usual course of conduct by inducing suppliers into exclusivity agreements that restricted such sales to generic manufacturers and generic competition suffered as a result.

D. Celgene Abuses the United States Patent System to Extend its Monopoly

251. Celgene's efforts to delay generic Revlimid did not end once a generic manufacturer managed to obtain the samples necessary to formulate a generic and file an ANDA. Celgene further sought to delay generic Thalomid and/or Revlimid by obtaining and asserting invalid patents that it used to delay the approval of prospective generic competitors. Celgene's patents were subject to strong invalidity and unenforceability arguments, including the key patents on which Celgene relied to exclude generic competition, namely the '517 compound Patent and the polymorph patents.

1. The '517 Patent is Invalid as Patently Obvious In View of the Prior Art

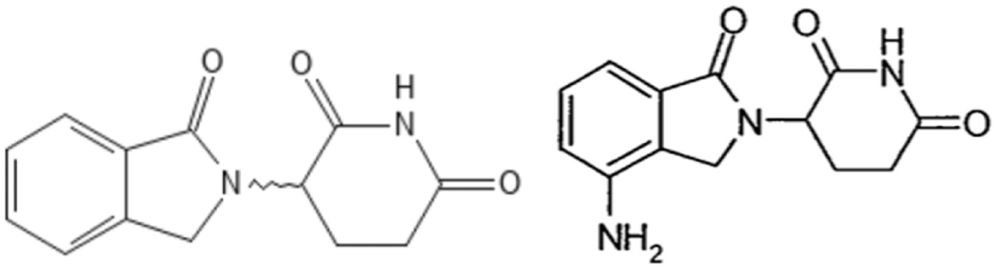
252. The original, core patent for the composition of Celgene's thalidomide-derived drugs is the '517 Patent, filed in 1996. It expired on October 4, 2019. Thalidomide, the drug on which Revlimid is based, was first marketed in 1957. The innovations on which the '517 Patent is based are obvious in light of the innovations and research conducted long before Celgene began its effort to bring Revlimid and Thalomid to market; thus, the '517 Patent and the subsequent patents derived from it are invalid.

253. A person working in the relevant field would have identified thalidomide and its analogs as effective in treating a variety of conditions. It would have been a natural choice to select EM-12 and/or 4-aminothalidomide as lead compounds for further development efforts, due to their favorable properties. And lenalidomide, the active ingredient in Revlimid, differs from these two lead compounds, EM-12 or 4-aminothalidomide, only by the addition of an amino group or the subtraction of an oxygen atom, respectively. Such modifications were obvious

because a person of ordinary skill would be motivated to make these small changes to EM-12 or 4-aminothalidomide by a desire to improve stability and/or solubility. A person of ordinary skill would have had a reasonable expectation of success that such modifications would produce a compound with beneficial properties due in part to the close structural similarity of the lead compounds to the claimed compound.

254. EM-12 is structurally similar to lenalidomide, differing only in the presence of an amino group (NH_2) at the 4-position of the phthalimidine ring:

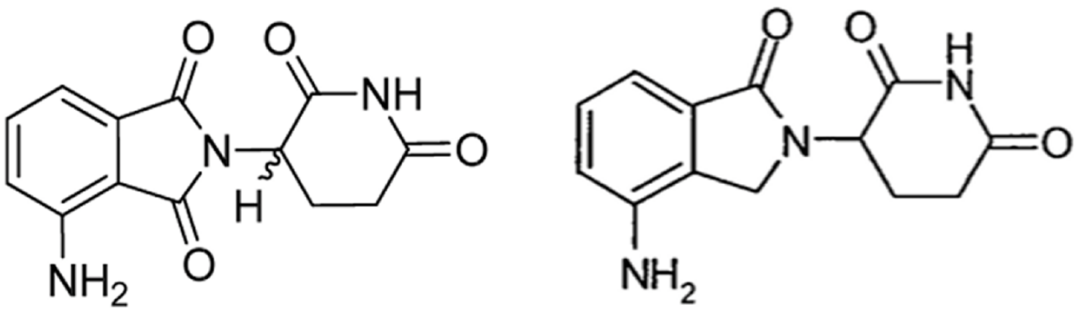
EM-12 **Lenalidomide**[117]



255. A person skilled in the art would be motivated to make the small structural change of adding an amino group to EM-12 at this particular location—a routine and easy change to make to the compound—as part of the standard steps in drug development and optimization.

256. 4-aminothalidomide is structurally similar to lenalidomide, differing only in that lenalidomide has one fewer oxygen atom than 4-aminothalidomide:

4-aminothalidomide **Lenalidomide**



257. It has been well known in the scientific community for decades that thalidomide analogs have a tendency to undergo hydrolysis (*i.e.*, degradation in the presence of water) and

[117] *See* Revlimid labeling information submitted by Celgene to the FDA at p. 5, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2005/021880s000_Revlimid_Prntlbl.pdf.

therefore one skilled in the art would have been motivated to make the well-known modification of subtracting the oxygen atom from this location to reduce the chance of hydrolysis and thereby promote stability. Indeed, the subtraction of an oxygen atom from this location is how one would obtain EM-12 from thalidomide, with the resulting compound having a superior stability profile as compared to thalidomide.

258. A person skilled in the art would have been motivated to make these minor changes at the specified locations with a reasonable expectation of success in creating a compound with beneficial properties based on the structural similarity of the lead compounds (EM-12 and 4-aminothalidomide) to lenalidomide; the teachings of the prior art regarding known modifications to improve the compound's chemical properties (*e.g.,* stability and solubility); the nature of the small changes at issue (*i.e.,* either the addition of an amino group or the subtraction of a single oxygen atom); and the totality of the prior art on thalidomide analogues (including EM-12 and 4-aminothalidomide specifically). Accordingly, the '517 claim for the lenalidomide compound is obvious in light of the prior art and therefore invalid.

2. The '517 Patent Would Have Been Invalidated But For Celgene Knowingly and Willfully Misleading the USPTO During Reexamination

259. The '517 Patent has ten claims. Claims 1-9 claim methods-of-use as to six compounds. In contrast to these method-of-use claims, Claim 10 of the '517 Patent claims four compounds, including lenalidomide. One of the method-of-use claims (Claim 8) pertains to pomalidomide. However, pomalidomide is not one of the compounds claimed in Claim 10 of the '517 Patent.

260. On April 14, 1998, Celgene filed a Request for Reexamination concerning the '517 Patent. Celgene "sought reexamination because of a question raised by a non-adversarial third party, a potential licensee, as to the significance of certain prior art." Celgene sought reexamination of claims 1-10 of the '517 Patent in view of: (l) D'Amato, U.S. Patent No. 5,593,990 issued Jan. 14,1997; (2) D'Amato, U.S. Patent No. 5,629,327; and (3) D'Amato, U.S. Patent No. 5,712,291 (together, "the D'Amato Patents"); and (4) Leibovich, *et al.*, U.S. Patent No. 4,808,402 and (5) Leibovich, *et al.,* Macrophage-lnduced Angiogenesis is Mediated By

Tumor Necrosis Factor-α, Letters To Nature, Vol. 329, pages 630-632, pub. 15 October, 1987"(together, the "Leibovich References").

261. On November 11, 1998, the PTO granted the request for reexamination, explaining Celgene:

> [I]s correct to allege that all three of the primary references, namely, the D'Amato Patents possess the same disclosure and both of the ancillary references, namely, the Leibovich et al. Patent and Journal article possess essentially the same disclosure. . . . The requester alleges that the three D'Amato patents generically teach[] the compounds of the involved patent under reexamination and that both Leibovich et al. references may be relevant because they teach the concept of Tumor Necrosis Factors possess[ing] the unexpected ability to induce angiogenesis, which is related to the involved patent under reexamination, albeit with different compounds, which appears to have relevance. ***A substantial new question of patentability affecting claims 1-10 of United States Patent No. 5,635,517 is raised by the request for reexamination.*** (emphasis added).

262. On December 9, 1998, Celgene submitted its Statement as to why the newly disclosed prior art references did not render the '517 Patent invalid for obviousness, arguing:

> D'Amato clearly does not describe or suggest the compounds used in the claimed method defined by claims 1-9 or those recited in claim 10. Regardless of what compounds the D'Amato patents do disclose, however, those references cannot render obvious the claimed method of reducing TNFa levels. This is also true of Leibovich et al. and D'Amato in combination with Leibovich et al. The Patent Owner sought reexamination, not because it believed D'Amato was relevant, but because of a question raised as to the significance of D'Amato by a nonadversarial third party. While D'Amato may raise a substantial new question of patentability, and should be considered, it is submitted that the ultimate question of patentability must be resolved in the Patent Owner's favor with a finding confirming the patentability of claims 1-10. Favorable action is earnestly solicited.

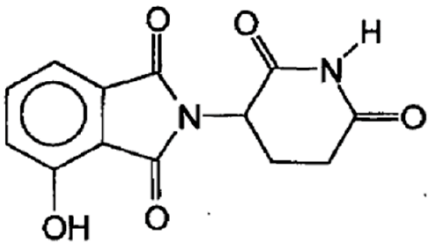
263. On February 22, 1999, the USPTO rejected all claims of the '517 Patent as unpatentable over the three D'Amato patents (the '990, '327, and '291 Patents) and in view of the two Leibovich references, finding, "***there is ample information in the prior [art] to motivate one of ordinary skill in the chemical arts to place [applicant's] compounds in possession of the public***." (emphasis added). Explaining its determination that the claims were unpatentable as obvious, the PTO stated:

> [T]he record has shown and the patentee has admitted in the record that the 3 D'Amato patents contain the same disclosure and said D'Amato patents supra disclose the very closely analogous compounds . . and methods for their preparation. . . . there is a teaching of equivalence between hydrogen, hydroxy, epoxy and amino as possible substituents on the 4,5,6 and 7 positions of the benzene ring of the said 1-oxo- or 1,3-dioxo-isoindoline ring. The concept of angiogenesis and administering said reference compounds to a patient with toxic concentrations of TNF-α is taught [in the D'Amato patents]. The [Leibovich references] represent an excellent reference for the known compound "thalidomide" which represents activation of macrophages, their relationship to angiogenic activity and a method of controlling abnormal concentrations of TNF-α factor associated with solid malignant tumors, benign tumors, leukemias and the like. . . . Since the properties of the prior art overlap with the ['517] under reexamination, and the 3-D'Amato patents teach the equivalents of hydrogen, hydroxy, epoxy and amino groups as substituents on each of the four positions on the benzene ring of the isoindoline nucleus, there is ample information in the prior [art] to motivate one of ordinary skill in the chemical arts to place applicants compounds in possession of the public.

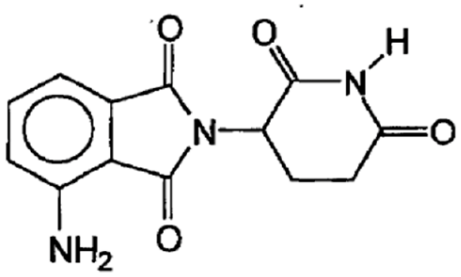
264. On February 25, 1999, Celgene submitted a Request for Reconsideration and attached a declaration from Dr. David I. Stirling, Celgene's then-Chief Scientific Officer and Executive Vice President (the "Stirling Declaration"). Celgene argued that any finding of obviousness was rebutted by the evidence of "unexpected properties" set forth in the Stirling Declaration.

265. The Stirling Declaration states in part: "Tests were conducted under my supervision to evaluate the relative activities of test compounds to inhibit the levels of [TNF-alpha]. . . . These tests were conducted on various compounds including the following:

Compound 1:



Compound 2:



266. The Stirling Declaration further stated: "I conclude that Compound 2 is >10,000 fold more active than Compound 1 in this primary human cell-based assay."

267. In its accompanying Request for Reconsideration, Celgene explained Dr. Stirling's findings, stating:

> As explained by Dr. Stirling, Compound 2 was >10,000 fold more active than Compound 1 in this assay. Compound 1 of course is the hydroxythalidomide compound of D'Amato; ***Compound 2 is the corresponding amino compound of the present claims***.

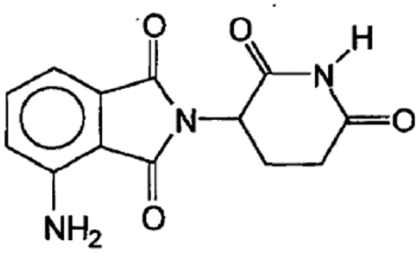
(emphasis added). Celgene concluded:

> [I]t is submitted that the D'Amato patents, alone or in combination with the Leibovich, *et al.* patent and publication, do not establish a prima facie case of obviousness. If, however, these references are deemed sufficient to establish a prima facie case of obviousness, it is believed the same has been fully rebutted by the evidence of record demonstrating unexpected properties.

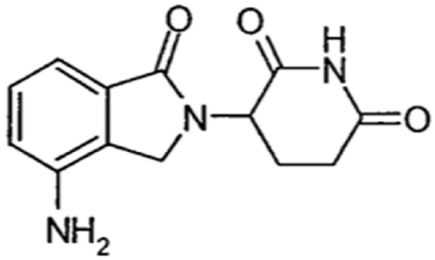
268. Shortly after Celgene's submission of the Request for Reconsideration and the Stirling Declaration, the USPTO issued a Notice of Intent to Issue Reexamination Certificate allowing the claims of the '517 Patent.

269. However, "Compound 2" is not lenalidomide, nor is it any of the other compounds claimed by the '517 Patent. "Compound 2" is pomalidomide,[118] *another* thalidomide analogue, which is not one of the compounds claimed by the '517 Patent.

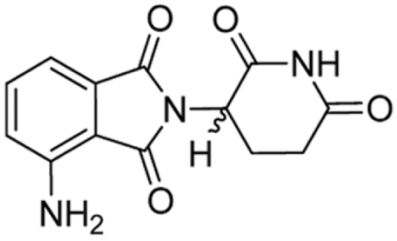
Compound 2:



Lenalidomide



Pomalidomide



[118] *See* Pomalyst labeling information submitted by Celgene to the FDA at p. 10, available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204026Orig1s000Lbl.pdf.

270. As shown above, lenalidomide has one fewer oxygen atom as compared to "Compound 2" referenced in the Stirling Declaration. The Stirling Declaration does not describe the testing of lenalidomide, or any of the other three compounds claimed by Claim 10 of the '517 Patent.

271. "Compound 2" is in fact pomalidomide, which is mentioned in Claim 8 of the '517 Patent as part of a method-of-use claim, i.e., "The method according to claim 7 in which said compound is 1,3-dioxo-2-(2,6-dioxopiperidin-3-yl)-4-aminoisoindoline." But the testing of "Compound 2" was irrelevant to the ***compound patent claims*** in Claim 10 of the '517 Patent. Celgene knowingly misled the PTO and breached its duty of candor by, *inter alia*, submitting testing that had nothing to do with the most vital part of the '517 Patent, *i.e.,* the compound claims of Claim 10.

272. Dr. Stirling states in his declaration that he performed testing on "various compounds." Yet, Dr. Stirling presented his findings with respect to only one comparator, *i.e.,* "Compound 1," which is a compound identified in the D'Amato patents. Celgene concealed the rest of the data and cherry-picked the results that would best support its claim of unexpected results.

273. In sum, the '517 Patent is invalid. After Celgene submitted the D'Amato and Leibovich references to the USPTO as part of the reexamination, the USPTO rejected all claims of the '517 Patent as invalid over the prior art. To overcome those obviousness rejections, Celgene submitted testing that purportedly showed unexpected results. However, the "unexpected results" did not pertain to any of the compounds claimed by the '517 Patent. Celgene failed to overcome the USPTO's finding of obviousness, and the compound claims of the '517 Patent are therefore invalid.

274. That Dr. Stirling intended to deceive the PTO is supported by the facts that: (i) he had detailed first-hand knowledge of Celgene's thalidomide analogue testing program generally, including the testing that had been done as to lenalidomide and related analogues, as well as the results of that testing program; (ii) he did not submit all of the testing results relevant to the issues raised during the '517 Patent examination; and (iii) he chose to present testing regarding a

compound *other than* one of the compounds claimed by the '517 Patent (*i.e.,* other than the compounds that would have supported allowing reexamination) in support of patentability.

275. At a minimum, the '517 Patent would have been found invalid by a court. The same facts would also support a finding of inequitable conduct by Dr. David Stirling (who signed and submitted the declaration) and potentially Celgene's in-house and outside counsel who submitted the Request for Reconsideration and supporting Stirling Declaration (Bruce M. Collins) and/or otherwise prosecuted the reexamination.

276. Celgene was able to overcome the PTO's conclusive findings of obviousness only by submitting the fraudulent Stirling Declaration. That declaration falsely stated that a compound claimed in the '517 Patent was surprisingly at least 10,000 times more active than hydroxythalidomide when, in fact, the tested compound was not even one of the four compounds claimed in the compound claim in the '517 Patent.

3. Celgene's Polymorph Patents are Also Invalid

277. To extend its monopoly on the sale of lenalidomide, Celgene began filing additional patent applications seeking to claim other polymorphic forms of lenalidomide. Polymorphs, also known as solvates or crystalline forms, of previously patented compounds are routinely developed as a standard practice in the pharmaceutical industry, according to a United States patent examiner in a rejection of one of Celgene's polymorph patent applications, and generally are not separately patentable.

278. Nonetheless, Celgene managed to get the USPTO to approve its polymorph patents and list them in the Orange Book. These patents—the '800 Patent and the '217 Patent—expire in 2027 and 2024, respectively. Since these patents have the latest expiration dates of any patents associated with Revlimid, they have been key patents cited in repeated attempts by Celgene and later BMS to block generic competitors from the market. Celgene routinely cites these polymorph patents against generic manufacturers that have filed generic Revlimid and/or Thalomid ANDAs.

279. Yet, Celgene and BMS are well aware that these patents are likely invalid and have repeatedly settled lawsuits brought on these polymorph patents instead of testing their strength in court for fear of the result. When Natco filed an ANDA for a generic version of lenalidomide on July 12, 2010,[119] Celgene brought suit against it and its marketing partners, Watson and Watson's subsidiary Arrow, claiming infringement.[120] The parties agreed to a *Markman* hearing to settle the meaning of disputed patent terms.[121]

280. Citing Celgene's own clarified definition of the term "hemihydrate," Natco amended its invalidity contentions to the '800 Patent, arguing that it was invalid for indefiniteness, lack of enablement, and lack of written description. When Celgene was unable to prevent Natco from raising these amended invalidity contentions, Celgene quickly settled with Natco with an anticompetitive reverse payment settlement agreement, described more fully below. Having learned a dangerous lesson, Celgene did what was necessary to avoid a similar *Markman* hearing to address the meaning of "crystalline" in its subsequent litigation against Dr. Reddy's and other generic manufacturers.[122]

281. Celgene knew that the overbroad terms of its redundant polymorph patents were insufficient to block generic competitors from bringing non-infringing products to market where the generic manufacturer had developed a suitable workaround to Celgene's patents. The claims of Celgene's other polymorph patent, the '217 Patent, also identify crystalline and hemihydrate

[119] *See* FDA ANDA Approval/Tentative Approval for ANDA 201452 (May 21, 2021), 1, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/201452Orig1s000TAltr.pdf.

[120] *See Celgene Corp. v. Natco Pharma Ltd*., No. 10-5197, 2015 WL 4138982 (D. N.J. Jul. 9, 2015). Celgene alleged that while Natco Pharma filed the ANDA, Arrow assisted Natco Pharma in preparing and filing the ANDA, and Watson prosecuted the ANDA before the FDA.

[121] A *Markman* hearing is a pretrial hearing before a federal district court judge during which the judge examines evidence from all parties and determines the appropriate meaning of relevant and disputed key words used in a patent infringement lawsuit. A *Markman* hearing is also known as a "claim construction hearing."

[122] Letter to Court, *Celgene Corp. v. Dr. Reddy's Laboratories Ltd.*, 2:16-cv-7704 (D.N.J. Mar. 23, 2018), ECF No. 77. On the date that its responsive Markman pleadings were due, Celgene filed a letter informing the court that it resolved its claim construction disputes with Dr. Reddy's and would not be filing responsive pleadings.

forms of lenalidomide and are invalid for the same reasons as the '800 Patent. Celgene has entered stipulations dismissing claims based on the '217 Patent and/or executed a covenant not to sue on the '217 Patent in actions against eight separate generic manufacturers.[123] As a result, Celgene has shielded the '217 Patent, and the patents derived therefrom, from judicial scrutiny and invalidation. Nonetheless, Celgene continues to sue generic rivals on the '217 Patent solely to delay generic entry.

282. These patents, like the '517 Patent from which they were derived, were obtained only because the applicants failed to disclose publicly available prior art and research from decades earlier, which anticipate and invalidate the patent.[124] Celgene's failure to disclose such prior art provides an independent basis for invalidity. The polymorphs are also obvious variants of the composition of matter patent, adding a further basis for invalidity. Finally, based on Celgene's representations in the *Markman* hearing held in the Natco litigation, the claims of the patent are unenforceable as overbroad.

4. The Federal Circuit Has Invalidated Celgene's Key REMS Patents and Celgene Has Abandoned Attempting to Enforce the Rest

283. The '501 and '720 Patents covering Celgene's REMS program on Thalomid and Revlimid were invalidated by the Patent Trial and Appeal Board ("PTAB") on October 26, 2016.[125] Celgene's other REMS patents are also invalid. Celgene stopped pressing its other REMS patents in litigation against generics after the Federal Circuit affirmed the PTAB decision.

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[123] *See* Statement, *Celgene Corp. v. Natco Pharma Ltd.,* No. 2:10-cv-05197, ECF No. 140 (D.N.J. Aug. 31, 2012); Statement, *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.,* No. 2:17-cv-06842, ECF No. 81 (D.N.J. Aug. 8, 2018); Statement, *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc. et al.,* No. 2:17-cv-02528, ECF No. 93 (D.N.J. Aug. 8, 2018); Stipulation and Order of Dismissal, *Celgene Corp. v. Cipla Ltd.,* No. 2:17-cv-06163, ECF No. 63 (D.N.J. Aug. 16, 2018); Statement, *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al.,* No. 2:18-cv-11630, ECF No. 50 (D.N.J. Jan. 22, 2019); Consent Judgment, *Celgene Corp. v. Apotex Inc.,* No. 2:18-cv-00461, ECF No. 63 (D.N.J. Apr. 30, 2019); Stipulation and Order of Dismissal, *Celgene Corp. v. Hetero Labs Ltd. et al*., No. 2:18-cv-17463, ECF No. 54 (D.N.J Jan. 21, 2020); Statement, *Celgene Corp. v. Mylan Pharmaceuticals Inc. et al.,* No. 1:20-cv-00003, ECF No. 120 (N.D. W. Va. Oct. 9, 2020).

[124] Celgene had three polymorph patents that were not listed in the Orange Book, the '357, '219, and '598 Patents. These patents are also invalid as anticipated.

[125] *See Coalition for Affordable Drugs VI LLC, et al., v. Celgene Corp.,* IPR2015-01092, Paper

284. The PTAB found the ’501 Patent invalid as obvious over the combined disclosures of three asserted prior art references as representative of the level of ordinary skill in the art.

285. The PTAB also found the ’720 Patent invalid as obvious over the combined disclosures cited against the ’501 Patent for the original S.T.E.P.S. program, while finding that the inherent dangers of Thalidomide would drive someone of ordinary skill in the art to proactively improve the system. Citing U.S. Patent No. 5,832,449 (issued Nov. 3, 1998, “Cunningham”), which describes an approval code used by prescribers and pharmacies to track and manage pharmaceutical products, the PTAB found that a person of ordinary skill in the art could predict that such an approval code could be utilized by prescribers and pharmacies to track and manage Thalomid and Revlimid. In light of this prior art, the PTAB invalidated the ’720 Patent as obvious.

286. As the PTAB noted, “[w]hen it benefitted [Celgene’s] interests before [the] FDA, [Celgene] freely admitted that its ‘plan [for thalidomide] is built on experience with restrictions on such other drugs with severe adverse effects as Accutane … and Clozaril.”[126] Before the USPTO however, Celgene repeatedly failed to disclose the very materials that it relied on in presenting its program to the FDA, along with other similar prior art such as the Clozaril Patient Monitoring Service and numerous published works describing the features of the REMS programs similar to Celgene’s original and modified S.T.E.P.S. programs.

287. On July 30, 2019, the Federal Circuit affirmed the findings of the PTAB invalidating the ’501 and ’720 Patents for obviousness.[127]

288. The ’976 Patent, the ’977 Patent, and the ’784 Patent, filed more than three years later, are nearly identical to the invalidated ’501 and ’720 Patents. In fact, many of these patents

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No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01092; IPR2015-01096, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01096; IPR2015-01102, Paper No. 75 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01102; IPR2015-01103, Paper No. 76 (Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01103 (“*Coalition*”).

[126] IPR2015-01092, at 24 (P.T.A.B. Oct. 26, 2016).

[127] *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019).

were so similar that Celgene did not even bother changing the title or abstract describing the patent.

289. The ’501, ’720, ’976, ’977, ’784, ’886 and ’399 Patents are similarly unenforceable due to inequitable conduct because the applicants of these patents, as well as their agents, attorneys and/or others substantively involved in the prosecution of those patents, concealed from the USPTO prior art references that they knew were material to patentability with intent to deceive the patent examiner.[128]

290. As a patent related to and directed to an invention not sufficiently distinct from the unenforceable ’720, ’977, ’784, and ’399 Patents, the ’018, ’566, ’886 and ’531 Patents are likewise unenforceable under the doctrine of infectious unenforceability. In particular, each of the ’018, ’566, and ’531 Patents are terminally disclaimed over the ’720, ’977, ’784, and/or ’399 Patents, and the ’866 Patent is terminally disclaimed over the ’566 Patent.

5. Celgene’s “Method-of-Use” Patents Also Cannot be Used to Lawfully Block Generic Entry

291. The patent prosecution of the ’740 Patent reveals yet another example of Celgene abusing the patent system to extend its monopoly. There, Celgene wrongfully obtained method-of-use patents that should not have ever been issued and would have been invalidated at trial but for Celgene’s monopolistic scheme of routinely filing sham litigation only to settle before being subjected to judicial scrutiny.

292. Method-of-use patents are issued when an inventor has discovered a way to use either a patented or generic drug in a “novel, useful, and non-obvious” way.[129] The result is a

[128] Indeed, in denying Celgene’s motion to dismiss on October 20, 2015 in *In re Thalomid and Revlimid Antitrust Litigation*, Case No. 14-cv-6997-MCA-MAH (D. N.J.), the Court already determined that plaintiffs had “plausibly allege[d] that Celgene willfully omitted the prior art from the prior applications with the intent to deceive the USPTO” as to the ’501, ’720, ’976, ’977, ’784, and ’886 Patents. *Id.* at ECF No. 68 at 23. The Court also found that plaintiffs in that case had adequately alleged that Celgene sued generic manufacturers Barr and Natco “to enforce illegally obtained patents[.]” *Id.*

[129] Roger D. Blair & Anita N. Walsh, *Method-of-Use Patents, Appropriability, and Antitrust Policy*, 56 Rev. Indus. Org. 651 (Mar. 10, 2020).

medical procedure that is unique, not because of the drug, but because of the way that the drug is administered.[130]

293. Celgene's method-of-use patent 7,189,740 is a continuation of U.S. Application No. 10/411,649 filed Apr. 11, 2003. Application No. 10/411,649 stems from Provisional Patent Application No. 60/418,468 filed on October 15, 2002. Based on this information, one would understand the priority date for the '740 Patent to be October 15, 2002.

294. During the prosecution of what led to the '740 Patent, the USPTO rejected the claims as anticipated over U.S. Application No. 03/0235909 and U.S. Application No. 04/0067953 ("Stein"). The USPTO also rejected the claims as anticipated or obvious over WO 01/87307 and for double patenting over U.S. Application No. 10/438213.

295. To overcome the USPTO's rejection, Celgene filed a declaration by Dr. Jerome Zeldis, Celgene's then-Vice President and Chief Medical Officer, dated August 17, 2005 (the "First Zeldis Declaration"), which included the following statement by Dr. Zeldis:

> ***I conceived of the presently claimed invention in the '649 application prior to March 8, 2002***, the date of the first filed application to which Stein claims priority. This is evidenced by a clinical trial protocol identified within Celgene as 'MDS-501-001' which is entitled "A PHASE II OPEN LABEL STUDY OF THE SAFETY AND EFFICACY OF CC-5013 (REVIMID®) TREATMENT FOR PATIENTS WITH MYELODYSPLASTIC SYNDROME.' A redacted copy of the front page of this protocol description is attached hereto as Exhibit D. (emphasis added).

296. The First Zeldis Declaration continues with the following statement:

> Specifically, the protocol for treating MDS with REVLIMID® was designed based upon my conception, and under my supervision and direction, prior to March 8, 2002. Patients were enrolled and treated with REVLIMID® under the protocol from prior to March 8, 2002 to the filing date of the present application. This is evidenced, in part, by the abstract attached hereto as Exhibit E, List et al., 'High Erythropoietic Remitting Activity of the Immunomodulatory Thalidomide Analog, CC-5013, In Patients with Myelodysplastic Syndrome (MDS),' American Society of Hematology Abstract #353, 2002, which reports the results obtained under the protocol MDS-501-001. This study is also disclosed in Section 5.3. 'Clinical Studies In MDS Patients,' on pages 34-35 of the specification.

[130] *Id.*

297. Contrary to Dr. Zeldis's assertion, none of the cited references support his claim that he "conceived of the claimed invention prior to March 8, 2002." Exhibit D is a single page from the protocol, from which all date information has been conspicuously omitted:

Exhibit D

CONFIDENTIAL — CELGENE CORPORATION PROTOCOL MDS-501-001

A PHASE II OPEN LABEL STUDY OF THE SAFETY AND EFFICACY OF CC-5013 (REVIMID™) TREATMENT FOR PATIENTS WITH MYELODYSPLASTIC SYNDROME

PROTOCOL MDS-501-001

FINAL PROTOCOL DATE:

ORIGINAL PROTOCOL DATED:

Principal Investigator:	Signature of Investigator: By my signature, I agree to personally supervise the conduct of this study and to ensure its conduct in compliance with the protocol, informed consent, IRB/EC procedures, instructions from Celgene representatives, the Declaration of Helsinki, ICH Good Clinical Practices guidelines, and the applicable parts of the Code of Federal Regulations governing the conduct of studies. Alan F. List, M.D. Section of Hematology /Oncology Arizona Cancer Center University of Arizona Tucson, AZ 85724 Telephone: (520)626 2340 Facsimile: (520) 626 2415
Sponsor:	Celgene Corporation 7 Powder Horn Drive Warren, New Jersey 07059 Telephone: (732) 271-1001
Medical Monitor:	Robert Knight, M.D. Celgene Corporation 7 Powder Horn Drive Warren, NJ 07059 Telephone: (732) 805-3749 Facsimile: (732) 805-3623

298. Similarly, Exhibit E is an abstract from the December 6-10, 2002 annual meeting of the American Society of Hematology that describes a study but provides no information about the date of the study. The same is true for the referenced pages of the specification.

299. Subsequently, the PTO rejected the claims, *inter alia,* as obvious over a newly-cited prior art reference, Raza (August 2001, Blood), in view of WO 01/87307 (international publication date of November 22, 2001). In response, Celgene submitted a second declaration from Dr. Zeldis dated June 22, 2006 (the "Second Zeldis Declaration").[131]

[131] Patent file wrapper PDF at p. 794-796.

300. In *this* declaration, Dr. Zeldis claims, he "***conceived of treating MDS with Revlimid before July 19, 2001***."[132] For this, he cites the same Exhibits D and E and the same section of the specification. However, no exhibits are attached to the Second Zeldis Declaration; and as noted above, the referenced pages of the specification do not provide any date information. Shortly after the submission of the Second Zeldis Declaration, the '740 Patent issued (subject to terminal disclaimer as to U.S. Patent Application No. 10/438,213).[133]

301. Dr. Zeldis' claims were unsupported and fraudulent in that they were designed to induce the USPTO to issue the '740 Patent to further establish the patent fortress around Revlimid and insulate Celgene (and later, BMS) from generic competition.

302. During this period, Celgene improperly obtained sixteen method-of-use patents, many of which related to uses that were susceptible to "section viii carveouts" or "skinny labels."[134] Section viii of the Hatch-Waxman Act permits a generic manufacturer to limit the number of patents at issue in litigation by seeking ANDA approval on one or more of the FDA approved indications and omit from its label information about other approved indications.[135] Often a generic company includes in its label the original approved indication and omits additional indications that are claimed by patents with later expiration dates. The FDA and Congress encourage generic companies to use section viii carve outs in order to bring generic drugs to market as soon as possible.

303. Based on publicly available final and temporary FDA approval letters, it is apparent that would-be generic entrants were contemplating and/or employing this strategy.

304. The following lists the publicly available methods-of-use patents that have been carved out by each generic manufacturer as to Revlimid:

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[132] *Id.* (emphasis added).

[133] Terminal disclaimer dated June 23, 2006 (patent file wrapper PDF at p. 792).

[134] See 21 U.S.C. § 355(j)(2)(A)(viii).

[135] *Id.*

Generic	Section viii Carve Outs
Lotus	’363, ’406, ’929, ’730, and ’238 Patents
DRL	’363, ’406, ’929, ’730, and ’238 Patents
Natco	’363, ’406, ’929, ’730, ’238, and ’621 Patents

305. For instance, Natco’s Final Approval Letter confirms that it certified section viii carveouts for the ’406, ’621, ’730, and ’238 Patents. From the redacted text it also appears that Natco may have been contemplating a carveout for less common uses of the ’363 Patent, including for treatment of mantle cell lymphoma, follicular cancer, and marginal zone lymphoma.

306. Because all of Celgene’s methods-of-use patents are invalid, generic manufacturers would have only needed to address subsections of these patents to prevail at trial and bring a competing generic to market.

307. Further, Celgene’s multiple myeloma method-of-use patents (the 7,968,569, 8,530,498, 8,648,095, and 9,101,622 Patents) claim the administration of lenalidomide in combination with dexamethasone in specific dosing regimens. The initial non-provisional applications for these method-of-use patents claimed the benefit of a May 17, 2002 provisional application (Application No. 60/380,842) and a November 6, 2002 provisional application (Application No. 60/424,600).

308. The multiple myeloma method-of-use patents are particularly susceptible to a patent invalidity attack, including one based on obviousness. It was well known in the prior art before May 17, 2002 that lenalidomide in combination with steroids such as dexamethasone was used to treat various cancers. To overcome the USPTO’s rejections for obviousness, Celgene submitted findings it claimed showed that it had determined, before the date of its May 2002 application, that there were unexpected results in the administration of lenalidomide in combination with dexamethasone in specific dosing regimens. However, Celgene’s unexpected results were not, in fact, unexpected, nor did they post-date the claimed invention by a significant period of time.

309. For example, during Celgene's prosecution of the '569 Patent, it "submitted numerous publications" that supposedly supported that "the claimed combination therapy showed surprising, unexpected and synergistic effects for treating multiple myeloma patients." However, those publications all post-dated Celgene's claimed invention; Celgene failed to establish that it had shown unexpected results from such therapy at the time it submitted its patent application. Further, Celgene's references would not have substantiated a finding of patentability had they been subject to a fulsome patent invalidity litigation.

E. Celgene Files Baseless Citizen Petitions to Further Thwart Generic Competition

310. As part of its decades-long scheme to monopolize the market for Revlimid, Celgene filed baseless citizen petitions against generic manufacturers when manufacturers managed to secure the necessary API to file an ANDA. In filing such citizen petitions, Celgene knew that it is the standard practice for FDA to withhold ANDA approval until FDA completes its research into and response to a citizen petition. The filing of baseless citizen petitions occurred often in tangent with, and as a complement to, Celgene's sham patent litigations; both of these actions interfered directly with the generic manufacturers' ability to bring generic Revlimid to market.

311. To illustrate, on September 20, 2007, Celgene filed a citizen petition, urging the FDA not to approve Barr's thalidomide ANDA. Celgene submitted this citizen petition one year after Barr had filed its ANDA with the FDA for generic Thalomid and nine months after Celgene had filed a sham patent lawsuit. Celgene's citizen petition was baseless and intended to delay Barr's entry into the market for generic thalidomide.

312. In its citizen petition, Celgene requested that FDA withhold approval of any generic thalidomide product, or alternatively: (i) require the application for generic thalidomide to be subject to the same conditions of approval applied to Thalomid under Subpart H of 21 C.F.R. Part 314; and (ii) prohibit the restricted distribution program for the generic thalidomide product from authorizing prescriptions for, and registering patients with, multiple myeloma, in violation of Celgene's orphan drug exclusivity, which would expire in 2013.

313. Celgene's petition was of course meritless. It lacked any reasonable regulatory, scientific, medical, or other basis. The FDA lacked statutory authority to withhold approval of generic thalidomide on the bases given by Celgene or to require the actions Celgene requested. Like its litigation against Barr, this citizen's petition was a sham designed to maintain Celgene's monopoly. Indeed, Celgene knew, Barr knew, and even the FDA knew this to the be the case. In a later meeting with Celgene in 2012, the FDA's Jane Axelrad, Associate Director for Policy at the Center for Drug Evaluation and Research or CDER, expressed that "since 2007, Celgene's citizen's petition states there are safety concerns and this is because the company does not want generics on the market."[136]

314. On December 19, 2008, Barr responded to the petition, pushing back on Celgene's petition and arguing that it "is nothing more than yet another attempt by a brand company to block all generic competition using market exclusivity protecting just a single approved indication."[137] Barr explained that Celgene's pretextual safety concerns were "hyperbole designed to improperly play on the public's fears regarding thalidomide," and that Barr's proposed thalidomide would be safe and its label would contain all precautionary information contained in the Thalomid label. Specifically, Barr argued that the law permits it to carve-out from its label Thalomid's protected MM indication, and that "Barr's Thalidomide Labeling Need Not Contain The Multiple Myeloma Indication To Ensure The Safe And Effective Use Of The ANDA Product."

315. Nearly six years later, on September 30, 2014, the FDA finally denied Celgene's citizen petition. Specifically, it "den[ied Celgene's] request that [the] FDA decline to approve any ANDA for thalidomide."

316. Celgene's filing of baseless citizen petitions was part of, and advanced, its scheme to monopolize the market for Revlimid.

[136] Mylan Opp. at Ex. P9, ECF No. 285-15 at 44-45 (CELMN-FREJ-000103857-858).

[137] Mylan Opp., ECF No. 285-1 at 54 (referencing CELM-BROF-000048325).

F. Celgene and BMS Initiate Serial "Sham" Patent Infringement Lawsuits Against Potential Generic Competitors

317. In addition to the abuses outlined above, Celgene brought serial patent litigation against its potential generic competitors without regard to the merit or likely outcome of those lawsuits, simply to obtain the benefits of the 30-month stay of FDA approval.[138] Many of those lawsuits were ultimately settled by means of unlawful reverse payments. As described in more detail below, Celgene, Natco, and Natco's marketing partners executed an unlawful reverse-payment/output-restriction/market-allocation agreement regarding Revlimid in 2015. Partly as a result of the MFEP included in that agreement, Celgene induced numerous later-filing generics—including, Dr. Reddy's—to enter into similar settlement agreements to fulfill the expectations of the parties to the initial Natco agreement.

318. To date, after over 13 years of litigation comprising more than 30 separate actions, Celgene and BMS have not allowed a single patent for lenalidomide to face judicial scrutiny and judgment in a trial before a district court.[139] The last filed patent litigation, against Alembic Pharmaceuticals, settled just last year, in July 2022.

319. In 2010, Celgene filed a patent lawsuit against Natco for its lenalidomide ANDA. In 2016, Celgene filed a patent lawsuit against Dr. Reddy's for its lenalidomide ANDA. In 2017, Celgene filed patent lawsuits against Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare Ltd. (collectively, "Zydus"), Cipla Ltd. ("Cipla"), Lotus Pharmaceutical Co., Ltd. and Alvogen Pine Brook, LLC (collectively, "Alvogen"), and again against Dr. Reddy's for their lenalidomide

[138] Celgene's pattern and practice of bringing sham patent infringement lawsuits against its would-be generic competitors was not limited to Revlimid. For example, in 2011, Celgene sued Mylan, Intellipharmaceutics Corp., and Par Pharmaceutical, Inc., among others, for patent infringement over its patented drug Focalin XR (generic dexmethylpenidate hydrochloride), which is used to treat ADHD. All lawsuits settled in relatively short order and without testing Celgene's patents. *See Celgene Corp. v. Mylan Pharm Inc.*, Case No. 11-cv-1882-SDW-MCA (D. N.J.); *Celgene Corp. v. Intellipharmaceutics Corp.*, Case No. 11-cv-1736-ES-CLW (D. N.J.); *Celgene Corp. v. Par Pharm., Inc.*, Case No. 11-cv-3094 (D. N.J.).

[139] This is perhaps not surprising given that studies estimate 89% of the patents that are the subject of pay-for-delay settlements involve "secondary patents" that are unlikely to hold up once challenged. *See* Jones, G., Carrier, M., Silver, R., and Kantarjian, H., *Strategies that delay or prevent the timely availability of affordable generic drugs in the United States*, Blood (Mar. 17, 2016), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915805/ (last visited Aug. 29, 2023).

ANDAs. In 2018, Celgene filed patent lawsuits against Apotex Inc. ("Apotex"), Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, Hetero Drugs Ltd., and Hetero USA, Inc. (collectively, "Hetero"), twice against Sun Global FZE, Sun Pharma Global Inc., Sun Pharmaceuticals Industries, Inc., and Sun Pharmaceutical Industries Ltd. (collectively, "Sun"), again against Alvogen, Dr. Reddy's, Cipla, and Zydus for its lenalidomide ANDAs. In 2019, Celgene filed patent lawsuits against Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. (collectively, "Mylan"), and again against Cipla, Hetero, and twice against Apotex. In 2020, Celgene filed patent lawsuits against Lupin Ltd. ("Lupin"), and again against Mylan and Hetero. In 2021, Celgene filed patent lawsuits against Hikma Pharmaceuticals USA, Inc. ("Hikma"), Aurobindo Pharma Ltd., Eugia Pharma Specialties Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Aurobindo"), Torrent Pharmaceuticals Ltd. and Torrent Pharma Inc. (collectively, "Torrent"), Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc. (collectively, "Biocon"), Lupin Ltd., and Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. (collectively, "Alembic").

320. In each case, Celgene alleged that the proposed generic versions of Revlimid infringed Celgene's patents. Each generic defendant counterclaimed, alleging that Celgene's patents were invalid as anticipated or for obviousness, or for lack of written description, under 35 U.S.C. §§ 101, 102, 103 and/or 112, and general principles of patent law, and/or were not infringed. Because Celgene knew that its patents were invalid, it also must have known that the litigation to enforce the invalid patents would be unsuccessful. Celgene brought the actions only because doing so would delay generic entry.

321. As detailed above, Revlimid was one of the key assets acquired by Bristol-Myers Squibb in its acquisition of Celgene on November 20, 2019. Beginning in November 2019, BMS[140] adopted and ratified the prior unlawful actions taken by its wholly owned subsidiary and

[140] BMS, like Celgene, has resisted efforts to rein in the prices of brand pharmaceuticals, including suing the federal government in an attempt to block Medicare from being able to negotiate the price for brand pharmaceuticals under the Inflation Reduction Act. *See* Compl. in *Bristol Myers Squibb Co. v. Becerra*, Case No. 23-cv-3335 (D. N.J.).

became a party in its own right to the continuing conspiracy in restraint of trade and scheme to monopolize alleged in this Complaint.

G. Celgene and BMS Conspire with Natco/Teva and Dr. Reddy's to Resolve Meritless Patent Litigation by Colluding to Artificially Allocate the Revlimid Market on Anticompetitive Terms

1. Celgene Grants Natco/Teva an Anticompetitive Slice of the 5, 10, 15, and 25 mg Revlimid Market

322. Natco initially filed an ANDA with the FDA for generic lenalidomide in the 2.5, 5, 10, 15, 20, and 25 mg strengths on or about July 12, 2010.[141] Several months later, in December 2010, Natco announced a marketing and development agreement for generic Revlimid with marketing partner, Watson, and Watson's subsidiary, Arrow International Limited ("Arrow").

323. On August 30, 2010, Natco sent a Paragraph IV Certification to Celgene, which contained a detailed factual and legal statement as to why Celgene's REMS patents, and the '517, '230, '554, '106, and '800 Patents, were invalid, unenforceable, and/or not infringed by Natco's proposed generic Revlimid.[142]

324. On October 8, 2010, Celgene filed a patent infringement suit against Natco in the District of New Jersey.[143]

325. Celgene continued to pursue new patents for its Revlimid product. In 2012, it listed two new patents in the Orange Book, a formulation patent (Patent No. 8,288,415) and another REMS patent (Patent No. 8,315,886). In response, Natco sent Celgene an additional Paragraph IV Certification on March 14, 2013, containing a detailed factual and legal statement as to why the '415 and '866 Patents were invalid, unenforceable, and/or not infringed by Natco's generic Revlimid product.

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[141] *See* ANDA Approval/Tentative Approval, FDA, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/201452Orig1s000TAltr.*pdf* (last visited Sep. 13, 2023).

[142] Answer and Counterclaims to First Am. Compl., *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. Jan. 14, 2010).

[143] Compl., *Celgene Corp. v. Natco Pharma Ltd.,* No. 10-5197 (D.N.J. Oct. 8, 2010).

326. On April 10, 2013, Celgene caused Patent No. 8,404,717 to be listed in the Orange Book for Revlimid. The '717 Patent is a method-of-use patent for the treatment of myelodysplastic syndromes using lenalidomide.

327. On May 6, 2013, Celgene filed an amended complaint (its Fifth Amendment Complaint) against Natco.[144] Celgene alleged that Natco's generic Revlimid product would infringe the Revlimid REMS patents, as well as the '886 Patent, the '517, '230, '554, '106, '800, '415, '717 and '598 Patents. Natco denied these allegations and argued that the '517, '230, '554, '106, '800, '415, '717 and '598 Patents were invalid and that its proposed generic lenalidomide product did not infringe Celgene's '800 Patent because Natco's proposed generic product did not contain lenalidomide hemihydrate. Natco also filed counterclaims alleging invalidity and unenforceability of Celgene's patents.

328. Meanwhile, Celgene abandoned its efforts to assert many of its ill-gotten and invalid patents. On January 20, 2011, Celgene informed the court that it covenanted not to sue Natco on the '326 Patent and '432 Patent.[145] On August 31, 2012, Celgene did the same for the '217 Patent, which, along with the '800 Patent, is one of Celgene's two key polymorph patents.[146] And on September 26, 2012, Celgene covenanted not to sue Natco on the '763 Patent.[147] In exchange, Natco dropped its counterclaims of invalidity against Celgene.

329. The court conducted a *Markman* hearing on May 15, 2014. On May 27, 2014, the Honorable Susan D. Wigenton issued a *Markman* Opinion resolving disputed claim definitions in

[144] Am. Compl. (Fifth), *Celgene Corp. v. Natco Pharma Ltd.*, No. 2:10-cv-05197, ECF No. 215 (D. N.J. May 6, 2013).

[145] Statement, *Celgene Corp. v. Natco Pharma Ltd*., No. 2:10-cv-05197, ECF No. 24 (D.N.J. Jan. 20, 2011).

[146] *Id.* at ECF No. 140 (D.N.J. Aug. 31, 2012).

[147] *Id.* at ECF No. 145 (D.N.J. Sep. 26, 2012). In its Answer, Natco provided twenty-six pages of prior art references that render the '763 Patent invalid and/or unenforceable. 2:12-cv-04571, ECF No. 15, Ex. B (D.N.J. Sep. 28, 2012).

Natco's favor on three of the five disputed terms at issue.[148] The rulings included narrow constructions of certain claim terms of the '554, '230, '357, and '598 Patents, likely permitting Natco to prevail on a noninfringement theory as to these pharmaceutical patents ('554 and '230 Patents) and polymorph patents ('357, and '598 Patents). Indeed, after issuance of the *Markman* Opinion, Celgene stipulated to the dismissal of the '554 and '230 Patents.

330. Natco's strategy also included an attack on the '800 and '217 Patents, two polymorph patents that expire in 2027 and 2024, respectively.[149] As discussed above, these patents are invalid for obviousness. Nonetheless, Natco also alleged that it had invented around these patents. The polymorph patents, including the '357 and '598 Patents, claim multiple different polymorph embodiments of lenalidomide, which are labeled "Form A," "Form B," all the way through "Form H," The different polymorph embodiments differ based upon their levels of solvation or hydration. For instance, Form A is "unsolvated" and Form B is "hemihydrated." They also differ based upon specific testing results (such as X-Ray powder diffraction) that serve as "fingerprints" or identifying characteristics of each different polymorph.

331. Celgene argued that these embodiments were not claimed, specific polymorphs, but merely exemplars. In arguing for this (rejected) construction, Celgene's counsel revealed how difficult it would be for Celgene to prove infringement if specific polymorphs were claimed by listing the numerous specifications that an ANDA would need to have, specifically:

> This is what they're talking about reading in. So I don't know how you would put the chart in there, but you'd have to put words to it. And they'd have another one, and another one, and another one, and another one, and another one, and another one, and another one, and another one, and it's just keeps going. This is all the material they are suggesting should be read into this claim, this term, to define Form A. My finger is getting tired, but I'm almost done. This is what is the claim would look like with—and it's not even all of it because we couldn't fit it on one slide.[150]

[148] *Markman* Op., *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. May 6, 2013), ECF No. 312.

[149] As above, Celgene covenanted not to sue on the (earlier expiring) '217 Patent.

[150] Tr., *Celgene Corp. v. Natco Pharma Ltd.* No. 10-5197 (D.N.J. May 20, 2014), ECF No. 310 at 84.

In other words, unless Natco (or another generic's) product had each of the innumerable characteristics, it would not infringe.

332. The Court rejected Celgene's attempt, limiting "Form A to mean a particular polymorph with these distinguishing characteristics." This cleared the way for Natco to prevail on noninfringement where its ANDA did not exhibit *each and every* characteristic specified of the disclosed polymorph forms—an unlikely proposition as demonstrated by Celgene's own arguments at the *Markman* hearing.

333. In addition, the '800 Patent included the disputed term "hemihydrate." Natco argued that the term required an exact water to compound ratio of 0.5 to 1, which would have further limited the claimed polymorphic crystal form to what is called "Form B." Celgene argued that "hemihydrate," as used in the patent, implied an *approximate*, rather than exact, ratio. Under either construction, Natco's accused products *do not infringe* because they are an "anhydrous" form, *i.e., a form that has no water* in the crystal.

334. In the Court's *Markman* Opinion, the Court adopted Celgene's proposed definition, reading "hemihydrate," as a term of approximation.[151] Nevertheless, Celgene could only prove infringement of Natco's anhydrous product by arguing that *at some point* (such as after ingestion) Natco's product *would become* hemihydrated and infringe. However, by arguing for this broader definition of hemihydrate to bolster its weak and speculative infringement argument, Celgene exposed the '800 Patent to new invalidity defenses.

335. Less than a month after the *Markman* hearing, Natco moved to amend its answer to add invalidity of the '800 Patent for indefiniteness, lack of written description, and lack of enablement.[152] It argued that in light of the Court's definition reading "hemihydrate," as an approximation: (1) a person of ordinary skill would be unable to determine the scope of the patent, (2) the patent did not disclose or suggest to a person of ordinary skill in the art that any

[151] *Markman* Op., *Celgene Corp. v. Natco Pharma Ltd*. No. 10-5197 (D. N.J. May 27, 2014), ECF No. 312, at 6-7. (finding that hemihydrate means "a hydrate containing approximately half a mole of water to one mole of the compound forming the hydrate").

[152] Letter, 2:10-cv-05197, ECF No. 321 (D. N.J. June 19, 2014).

hemihydrate form of lenalidomide other than Form B even exists, let alone clearly convey that the patentee was in possession of other hemihydrated forms of lenalidomide, and (3) the patent does not disclose how to make a hemihydrated form, other than Form B, having the claimed characteristics.[153]

336. In its July 11, 2014 brief, Celgene vigorously opposed Natco's motion to amend its answer.[154] When Magistrate Judge Arleo granted Natco's motion,[155] Celgene immediately appealed the Opinion and Order, which would have ultimately required Celgene to answer the invalidity issues its own claim construction had created. Briefing on the appeal of the order granting the amendment extended into January 2015 before Judge Wigenton.

337. Meanwhile, Celgene stipulated to dismissing its claims and defenses as to the '230 and '554 Patents (following the Court's adoption of Natco's proposed claim terms regarding these patents), as well as the '106 and '415 Patents.[156]

338. On July 9, 2015, Judge Wigenton affirmed Magistrate Judge Arleo's Opinion and Order granting Natco's motion to amend to assert the new defenses created by the court's *Markman* Opinion.[157] The parties served expert reports in late summer 2015 and responsive expert reports in September 2015.[158] Shortly thereafter, some six years after litigation began, Celgene settled with Natco avoiding scrutiny of the infringement or invalidity of any of its patents.

[153] *Id.* at 3.

[154] Letter, 2:10-cv-05197, ECF No. 331 (D. N.J. July 11, 2014).

[155] Op., 2:10-cv-05197, ECF No. 366 (D. N.J. Nov. 18, 2014).

[156] Stip. of Dismissal, 2:10-cv-05197, ECF No. 402 (D. N.J. March 26, 2015).

[157] Op., 2:10-cv-05197, ECF No. 440 (D. N.J. July 9, 2015).

[158] *See* Am. Sched. Order, *Celgene Corp. v. Natco Pharma Ltd*. No. 10-5197 (D. N.J. May 6, 2013), ECF No. 449.

339. On December 22, 2015, Celgene announced the settlement of litigation with Natco and its marketing partners Watson and Arrow relating to Celgene's Revlimid patents.[159] Watson and its subsidiary were subsequently acquired by Teva when it acquired Actavis Generics from Allergan plc.

340. On or about May 21, 2021, Natco's ANDA for generic Revlimid was approved by the FDA, but only in the 5, 10, 15, and 25 mg strengths. Teva launched Natco's generic Revlimid a year later, in March 2022, pursuant to the terms of the unlawful December 2015 settlement agreement between Celgene and Natco.

341. At the time of the settlement, Celgene faced a substantial probability that Natco's lenalidomide product would be adjudged non-infringing, Celgene's patents would be invalidated, and/or Natco would launch its Revlimid generic "at risk." To avert the loss of its monopoly of lenalidomide products, Celgene bought off its would-be competitor, Natco.

342. The settlement agreement between Celgene, Natco, Watson, and Arrow included an anticompetitive reverse payment from Celgene to Natco, Watson, and Arrow. Celgene granted Natco and Watson a license to sell generic Revlimid in the 5, 10, 15, and 25 mg formulations[160] beginning in March 2022 with an MFEP clause, but only if Natco agreed to convert no more than 7% of the Revlimid market to generic units in the first year of its launch.

343. The agreement gradually increases the percentage of the market that Natco may capture each year until January 31, 2026, when the agreement expires. The settlement agreement also gave Natco access to Celgene's REMS program for Revlimid, thus giving Natco something of substantial value—and something it could not have obtained through patent litigation—for no payment whatsoever. The value of the settlement to Natco/Teva was large and far larger than the cost of patent litigation against Celgene.

[159] Press Release, Celgene Corp., *Celgene Settles REVLIMID® Patent Litigation* (Dec. 22, 2015), http://ir.celgene.com/releasedetail.cfm?ReleaseID=947998.

[160] Natco obtained FDA approval for the 5, 10, 15, and 25 mg formulations of generic Revlimid on May 21, 2021. *See Generic Revlimid Availability*, Drugs.com (updated on Aug. 9, 2023), *available at https://www.drugs.com/availability/generic-revlimid.html* (last visited Sep. 1, 2023). Natco did not obtain FDA approval for the 2.5 and 20 mg formulations until March 6, 2023.

344. Under their settlement agreement, Celgene and Natco agreed to delay full-fledged generic competition on all formulations of Revlimid until at least January 31, 2026. This agreement was both a reverse-payment agreement and a horizontal agreement to restrict output and allocate markets—a *per se* violation of the Sherman Act.

345. By both the terms and effect of the arrangement, Celgene agreed to share its monopoly rents with Natco as a *quid pro quo* for Natco's agreement to limit its share of the Revlimid market and to delay full competition until at least January 31, 2026. These terms guaranteed Natco a limited share of the market at supracompetitive prices. But for the reverse payment, Celgene and Natco would have agreed to an entry date no later than some time in 2019.

346. On December 22, 2015, Celgene announced in a press release:

> In settlement of all outstanding claims in the litigation, Celgene will permit entry of generic lenalidomide before the April 2027 expiration of Celgene's last-to-expire patent listed in the Orange Book for REVLIMID®. Celgene has agreed to provide Natco with a license to Celgene's patents required to manufacture and sell an unlimited quantity of generic lenalidomide in the United States beginning on January 31, 2026. In addition, Natco will receive a volume-limited license to sell generic lenalidomide in the United States commencing in March 2022. The volume limit is expected to be a mid-single-digit percentage of the total lenalidomide capsules dispensed in the United States during the first full year of entry. The volume limitation is expected to increase gradually each 12 months until March of 2025, and is not expected to exceed one-third of the total lenalidomide capsules dispensed in the U.S. in the final year of the volume-limited license under this agreement.[161]

The "mid-single-digit percentage" referred to in the release was in fact 7%.

347. Celgene and Natco kept the details of the payment terms secret from the Court, the public, and Plaintiffs.

348. On a February 12, 2016 earnings call, Natco further disclosed that the license referred to by Celgene in its announcement was royalty free. Natco also disclosed the inclusion of

[161] Press Release, *Celgene Settles REVLIMID Patent Litigation*, dated December 22, 2015, available at https://www.businesswire.com/news/home/20151222005986/en/ (last visited March 29, 2022).

an acceleration clause, allowing for earlier Natco entry triggered by the early introduction of other generic versions of lenalidomide.[162]

349. Individually and collectively, these payment terms are anticompetitive. First, the volume-limited royalty-free license restricts output and allocates the market by eliminating Natco's incentive to compete on price in order to increase volume, ensuring that generic prices would remain at supracompetitive levels even after generic entry. As Teva (Natco's marketing partner) explained in an earnings conference call, the settlement with Celgene set up a "profit share."[163] The royalty-free generic license plus the MFEP constitutes a large reverse payment from Celgene to Natco and Teva worth hundreds of millions of dollars. The MFEP clause also deters other generics from continuing to challenge Celgene's patents and provides assurance to Natco that it will receive the most favorable entry date and retain its lucrative exclusivity period.

350. The terms of the unlawful agreement also eliminated any incentive of Celgene (and later BMS) to introduce an AG, since launching an AG would simply convert brand purchases to generic purchases and defeat the purpose of the 7% limit.

351. Natco executives celebrated the profits it planned to make from the Revlimid settlement to investors:

> Revlimid looks like a blockbuster. If you look at the guidance that they have given they have given very obscene numbers on how big the brand will be, right now it is about 3.5 billion. I have seen projections in the US and globally I think it is doing 5, 6 billion, they are saying it will be a $8, $9 billion brand so I think it will stay and I am still very positive about it . . .[164]

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[162] *See* Natco Pharma Q3 FY 2016 Earnings Conference Call" February 12, 2016, *available at* https://natcopharma.co.in/wp-content/uploads/2016/02/NirmalBang-NatcoPharma-Feb12-2016.pdf ("… if something triggers a launch date earlier than 2022 so the agreement has standard accelerated clauses with respect to everything, so if such an event were to happen so it is 22 limited quantity which will increase over a period of time to unlimited quality till 26 or in the event that something happens to the patents or certain events which are defined in our agreement, there are whole slew of events that are defined, standard accelerated clauses kick in which allows us an earlier entry as well.").

[163] *See* "Q1 FY 2019 Teva Pharmaceutical Industries Ltd. Earnings Conference Call" May 2, 2019, available at https://www.fool.com/earnings/call-transcripts/2019/05/02/teva-pharmaceutical-industries-limited-teva-q1-201.aspx.

[164] *Id.* at 20.

352. The settlement caused Natco to delay its bona fide full market entry until January 31, 2026.

353. On December 23, 2015 (the day on which the Revlimid settlement was announced) Celgene's stock price leaped upward by 9.8%, confirming the additional monopoly profits Celgene would gain from delayed competition. Stock prices reflect investors' expectations about a company's future profits. A dramatic upward change in the stock price reflects an upward revision in profit expectations. Generally, an increase in the brand's stock price after a patent litigation settlement indicates that the settlement delayed generic entry beyond investors' expectations.[165]

354. Celgene's stock price increase equated to a staggering increase in market capitalization of $8.6 billion, the single largest percentage increase in Celgene's stock price in 2015. Trends in the overall market do not explain the spike as the S&P 500 increased by only 1.2% on the same day. Natco's stock price went up too, increasing 2.3% on the Bombay Stock Exchange upon announcement of the settlement.[166] Without an alternative explanation, investors interpretation of the settlement as benefiting both Celgene and Natco indicates that joint profits were increased by delaying genuine generic competition.

2. Celgene and BMS Grant Dr. Reddy's an Anticompetitive Slice of the 2.5 mg and 20 mg Strength Revlimid Market

355. As part of its multifaceted, anticompetitive strategy, Celgene also filed three serial patent infringement suits against Dr. Reddy's for the sole purpose of delaying generic entry into the lenalidomide market. But for Celgene's anticompetitive scheme, Dr. Reddy's would have gained FDA approval far earlier and launched a competing generic Revlimid.

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[165] *See* Drake, Starr, and McGuire, *Do "Reverse Payment" Settlements Constitute an Anticompetitive Pay-for-Delay?*, International Journal of the Economics of Business, 22(2), 2015, pp. 173-200, and McGuire, *et al., Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements*, Iowa Law Review, 101, 2016, pp. 1581-1599.

[166] http://www.myiris.com/newsCentre/storyShow.php?fileR=20151223130747199&secTitle=activestock&arttype=news.

356. Dr. Reddy's initially filed an ANDA with the FDA for generic lenalidomide in the 2.5, 5, 10, 15, 20, and 25 mg strengths on or about July 12, 2016.[167]

357. On September 9, 2016, Dr. Reddy's sent Celgene a Paragraph IV Certification notifying Celgene that it had filed ANDA No. 209-348 with the FDA seeking approval to market generic Revlimid. On October 10, 2016, Celgene sued Dr. Reddy's in the District of New Jersey.[168] Celgene later sued Dr. Reddy's in two additional suits alleging infringement of Celgene's later-acquired patents.[169] Dr. Reddy's answered, in all three litigations, that the patents asserted were not duly or lawfully issued.[170]

358. On October 26, 2017, the parties filed a Joint Claim Construction Hearing and Prehearing Statement, in which Dr. Reddy's notified the court that "the construction of the claim term 'crystalline' will be 'most significant to the resolution of the case' and 'will be case or claim dispositive or substantially conducive to promoting settlement,' at least with respect to the '800 and '217 Patents on crystalline lenalidomide."[171] Although the '800 and '217 Patents are invalid for obviousness, Dr. Reddy's invented around these key patents (set to expire in 2024 and 2027) and its ANDA did not infringe Celgene's patents.

359. As detailed in its *Markman* brief, Celgene's Polymorph patents claim a "crystalline lenalidomide," but Dr. Reddy's ANDA product had an "amorphous lenalidomide" structure. Based on "the intrinsic and extrinsic record, as well as the understanding of the person

[167] *See* Oct. 14, 2021 ANDA Approval/Tentative Approval, FDA, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/209348Orig1s000ltr.pdf (last visited Sep. 13, 2023).

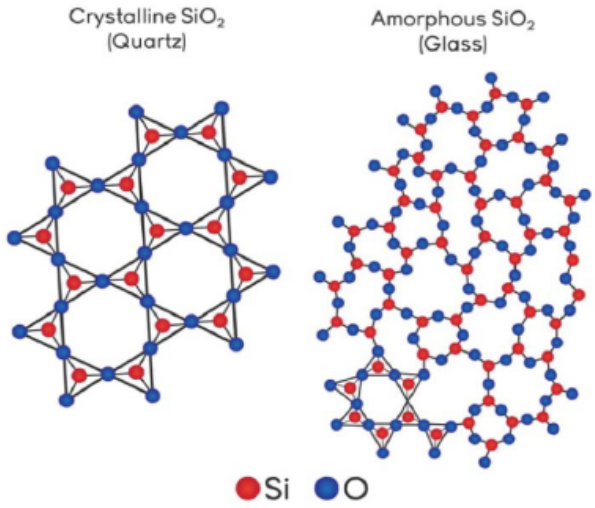
[168] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc*., No. 2:16-cv-07704 (D. N.J).

[169] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc*., 2:17-cv-05314 (D.N.J.); and *Celgene Corp. v. Dr. Reddy's Laboratories, Inc*., 2:18-cv-06378 (D. N.J.).

[170] *See* No. 2:16-cv-07704, ECF No. 7 (D.N.J. Nov. 18, 2016); 2:17-cv-05314, ECF No. 17 (D.N.J. Oct. 18, 2017); 2:18-cv-06378, ECF No. 30 (D. N.J. May 31, 2018).

[171] No. 2:16-cv-07704, ECF No. 57, at 4-5 (D. N.J. Oct. 26, 2017).

of skill in the art," Dr. Reddy's argued that amorphous structures "are not crystalline," but rather "composed of randomly oriented molecules with no long-range order."[172]



360. This distinction, likely establishing noninfringement, was further highlighted by the patents' prosecution history. Celgene initially attempted to include claims covering amorphous as well as crystalline forms, but, following rejection by the examiner, Celgene cancelled and removed the amorphous claims from the application.[173]

361. Celgene initially opposed Dr. Reddy's proposed construction. However, following briefing, on March 23, 2018, Celgene notified the court that the parties had resolved their claim construction disputes and would not be filing responsive *Markman* briefs.

362. On information and belief, Celgene conceded Dr. Reddy's construction of "crystalline," paving the way for Dr. Reddy's to argue that its ANDA did not infringe Celgene's key polymorph patents because, had Celgene opposed Dr. Reddy's construction (as in the Natco litigation), it would have opened its patents up to fatal invalidity arguments.

363. In PTAB proceedings, Dr. Reddy's also previewed winning invalidity arguments regarding Celgene's method-of-use patents for myelodysplastic syndromes. As a result, Dr. Reddy's had a clear path to market by using what is referred to as a "skinny label"—a label that

[172] No. 2:16-cv-07704, ECF No. 67, at 1, 4 (D. N.J. Dec. 22, 2017).

[173] ECF No. 67, at 4-5 (D. N.J. Dec. 22, 2017).

omits other indications to avoid patent infringement claims. Celgene's '740, '717, and '120 patents were anticipated by invalidating prior art, including press releases from years earlier.

364. Dr. Reddy's introduced two press releases bearing dates that would have invalidated the patent. In response, Celgene did not deny that the press releases were in fact published on the relevant dates, but instead disingenuously argued that the dates on the press release did not themselves establish that the press releases were published. While the PTAB denied invalidation on this technicality, Dr. Reddy's—and Celgene—knew that Dr. Reddy's could easily remedy this evidentiary technicality during District Court proceedings and invalidate Celgene's method-of-use patents.

365. On September 17, 2020, Celgene and BMS announced a settlement of the litigation with Dr. Reddy's.[174] Similar to Celgene's agreement with Natco, BMS's announcement provided only minimal details of the deal between BMS and Dr. Reddy's. As stated in BMS's press release:

> Celgene has agreed to provide DRL with a license to Celgene's patents required to manufacture and sell certain volume-limited amounts of generic lenalidomide in the U.S. beginning some time after the March 2022 volume-limited license date that Celgene previously provided to Natco. The specific volume-limited license date and percentages agreed-upon with DRL were not disclosed and are confidential. In addition, Celgene has agreed to provide DRL with a license to Celgene's patents required to manufacture and sell an unlimited quantity of generic lenalidomide in the U.S. beginning no earlier than January 31, 2026.[175]

366. On information and belief, the volume-limited caps agreed to by Celgene/BMS and Dr. Reddy's were the same as those Celgene agreed to with Natco/Teva: 7%. In addition, as with Natco/Teva, Celgene and BMS also granted Dr. Reddy's access to Celgene's REMS program for Revlimid.

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[174] *Bristol Myers Squibb Announces Settlement of U.S. Patent Litigation for Revlimid (lenalidomide) with Dr. Reddy's, available at* https://news.bms.com/news/details/2020/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID-lenalidomide-With-Dr.-Reddys/default.aspx (last visited Sep. 13, 2023).

[175] *Id.*

367. Dr. Reddy's CEO, Erez Israeli, told investors that he was "very pleased with the settlement."[176] He also advised investors that Dr. Reddy's "got the approval" for Revlimid with the FDA and were ready to launch in October 2021, but would not launch then "in accordance to our settlement agreement" with Celgene/BMS.[177]

368. Mr. Israeli's expressed joy over the settlement because the settlement was consistent with the MFEP included in the settlement with Natco and its marketing partners. In exchange for ending the patent litigation, Celgene carved out a portion of its monopoly to share with Dr. Reddy's, particularly the 2.5 mg and 20 mg formulations of generic Revlimid, over which Celgene granted Dr. Reddy's the exclusive (albeit volume limited) right to market.[178] In response to investor questions on October 29, 2021, Dr. Reddy's CEO shared his understanding that Dr. Reddy's was "entitled to exclusivity" on the 2.5 mg and 20 mg generic Revlimid products once they launched "in accordance to the settlement agreement" with Celgene/BMS.

369. The volume-limited caps ensure that Dr. Reddy's has no incentive to compete on price (because, like Natco, it could not benefit from any increased sales resulting from a price reduction). As with the Natco settlement, Celgene also has no incentive to launch an AG for these specific formulations. The net result of the agreement is to limit price competition and preserve Celgene's ability to sell brand Revlimid at monopoly prices.

370. Unfortunately, but not surprisingly given the anticompetitive nature of the agreement, the specific terms of Celgene's settlement agreement with Dr. Reddy's have been shielded from public review. Mr. Israeli, CEO, could not even initially inform his own investors

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[176] Dr. Reddy's Labs. Ltd. Q2 FY21 Earnings Conf. Call (Oct. 28, 2020), *available at* https://www.drreddys.com/cms/cms/sites/default/files/2021-08/earnings-call-transcript-q2-fy-21.pdf, at 12 (last visited Aug. 31, 2023).

[177] Dr. Reddy's Labs. Ltd. Q2 FY22 Earnings Conf. Call (Oct. 29, 2021), *available at* https://www.drreddys.com/cms/cms/sites/default/files/2022-03/earnings-call-transcript-q2-fy-22.pdf, at 6 (last visited Aug. 31, 2023).

[178] *Id.* at 9. Dr. Reddy's obtained FDA approval for the 2.5 and 20 mg formulations of generic Revlimid on October 14, 2021. *See Generic Revlimid Availability*, Drugs.com (updated on Aug. 9, 2023), *available at https://www.drugs.com/availability/generic-revlimid.html* (last visited Sep. 1, 2023). Dr. Reddy's did not obtain FDA approval for the 5, 10, 15, and 20 mg formulations until August 30, 2022.

of the timeline for the launch of Dr. Reddy's generic Revlimid products due to the confidential nature of the settlement agreement.[179] It wasn't until later earnings calls that it was confirmed that Dr. Reddy's and Celgene/BMS had agreed to a "volume limited launch" of generic Revlimid at the 2.5 and 20 mg formulations during September 2022 and then being permitted to sell "specific volume limited amounts of generic Lenalidomide" from September 2022 through January 31, 2026.[180] The specific volume limited amounts of generic Revlimid that Dr. Reddy's was permitted to sell was "rigid in the case that we can sell exactly the amount stated in agreement and the volumes and the market share is confidential."[181] On information and belief, the volume limitation was 7%.

371. To date, Dr. Reddy's agreement with Celgene/BMS has also forbid it from informing its own investors of the "specific sales volume or value" arising from Dr. Reddy's sales of generic Revlimid.[182] What is clear, however, is that Celgene/BMS gave Dr. Reddy's the exclusive right to sell a volume-limited amount of the 2.5 and 20 mg formulations of generic Revlimid—without any other competition—for longer than 180 days as more fully described below.

[179] *Id.*

[180] Dr. Reddy's Labs. Ltd. Q1 FY23 Earnings Conf. Call (Jul. 29, 2022), *available at* https://www.drreddys.com/cms/cms/sites/default/files/2022-08/Earnings%20Call%20Transcript%20-%20Q1%20FY%2023.pdf, at 5 (last visited Aug. 31, 2023).

[181] *Id.* at 12. When pressed, the CEO of Dr. Reddy's could not even share with investors whether the agreed-upon volume percentage was "calculated on an annual basis of calendar year basis." *Id.* at 14.

[182] Dr. Reddy's Labs. Ltd. Q2 FY23 Earnings Conf. Call (Oct. 28 2022), *available at* https://www.drreddys.com/cms/cms/sites/default/files/2022-11/Earnings%20Call%20Transcript%20-%20Q2%20FY%2023.pdf, at 4 (last visited Aug. 31, 2023); *see also* Dr. Reddy's Labs. Ltd. Q3 FY23 Earnings Conf. Call (Jan. 25, 2023), *available at* https://www.drreddys.com/cms/cms/sites/default/files/2023-01/DrReddys-Earnings-Jan25-2023.pdf, at 6 (last visited Aug. 31, 2023) ("I cannot share any numbers about the product, sorry. . . . Again, it's not because I would love to share but I can't. We have an agreement, and I have to honor that agreement.").

H. Celgene and BMS Protect Their Invalid Patents by Conspiring with Other Generic Manufacturers to Maintain Monopoly Pricing and Market Allocation

372. Celgene and BMS settled at least three later patent infringement suits against generic companies on terms that were consistent with and carried out the intentions of the parties to the initial Natco agreement. As explained further below, virtually all of the terms of the later generic settlements have been concealed from the public. None of the later-filing generics listed below entered the market before the March 2022 date agreed to in the initial Natco settlement.

373. Celgene's and BMS's actions in settling these other ANDA litigations served to preserve the ill-gotten gains and market allocation agreements with Natco and Dr. Reddy's, by, in part, ensuring that other generics accepted the March 2022 entry date of Natco into the 5,10,15, and 25 mg Revlimid market and the September 2022 entry date of Dr. Reddy's into the 2.5 and 20 mg Revlimid market (and did not try to leapfrog over either Natco or Dr. Reddy's to enter earlier with their own product) and forestalling robust generic competition until at least January 31, 2026.

374. As can be seen from the below table, to date, Celgene, BMS, and Natco have successfully capped market competition in the 5,10,15, and 25 mg Revlimid market to BMS and four generic competitors—Natco, Lotus, Cipla, and Zydus—even though at least six other generic competitors have received FDA approval to sell lenalidomide at those strengths. Natco, Lotus, Cipla, and Zydus have been able to maintain both artificially allocated market share and monopoly pricing as a result of the agreed-upon volume limitations dictated by Celgene and BMS.

375. As to the 2.5 and 20 mg Revlimid market, Celgene, BMS, and Dr. Reddy's have successful capped market competition to just BMS and two generic competitors—Dr. Reddy's and Lotus—even though at least eight other generic competitors have received FDA approval to sell lenalidomide at those strengths. Both Dr. Reddy's and Lotus have been able to maintain monopoly pricing as a result of the agreed-upon volume limitations dictated by Celgene and BMS.

Manufacturer	Revlimid Formulation	FDA Approval Date	Sales Date
Settlement Waves 1 and 2 for 5, 10, 15, and 25 mg			
Natco	5, 10, 15, and 25 mg	5/21/2021	3/2022
Lotus	5, 10, 15, and 25 mg	8/31/2022	9/2022
Cipla	5, 10, 15, and 25 mg	9/6/2022	9/2022
Zydus	5, 10, 15, and 25 mg	9/12/2022	9/2022
Apotex	5, 10, 15, and 25 mg	8/30/2022	*Unknown*
Sun Pharm	5, 10, 15, and 25 mg	2/8/2023	*Unknown*
Dr. Reddy's	5, 10, 15, and 25 mg	8/30/2022	*Unknown*
Settlement Waves 1 and 2 for 2.5 and 20 mg			
Dr. Reddy's	2.5 and 20 mg	10/14/2021	9/2022
Lotus	2.5 and 20 mg	3/6/2023	3/2023
Cipla	2.5 and 20 mg	3/6/2023	*Unknown*
Sun Pharm	2.5 and 20 mg	3/6/2023	*Unknown*
Zydus	2.5 and 20 mg	3/6/2023	*Unknown*
Apotex	2.5 and 20 mg	3/7/2023	*Unknown*
Natco	2.5 and 20 mg	3/6/2023	*Unknown*
Settlement Wave 3			
Aurobindo/Eugia	All formulations	3/6/2023	*Unknown*
Camber/Hetero Labs Ltd V	All formulations	5/11/2023	*Unknown*
Torrent	10 and 25 mg	2/17/2023	*after 10/2023*
Torrent	20 mg	8/3/2023	*after 10/2023*
Unknown Launch Date			
Mylan[183]	5, 10, 15, and 25 mg	8/30/2022	*Unknown*
Mylan	2.5 and 20 mg	3/6/2023	*Unknown*

1. Lotus Settles Patent Litigation with Celgene in Exchange for a Slice of the Generic Revlimid Market at Monopoly Pricing Beginning in September 2022

376. As part of its unlawful anticompetitive strategy, Celgene filed two serial patent infringement suits against Lotus Pharmaceuticals, Inc. and Alvogen, Inc. (collectively, "Lotus"). It brought the actions only to delay generic entry into the lenalidomide market. But for Celgene's anticompetitive scheme, Lotus would have gained temporary and final approval far earlier and would have launched a competing product earlier than it actually did.

[183] Mylan ultimately settled its antitrust lawsuit with Celgene on or about August 1, 2019 and the Court entered a consent judgment on August 8, 2019. Celgene disclosed that it had agreed to pay $62 million to resolve Mylan's claims. There was no reverse payment settlement with Mylan and, thus, Mylan likely cannot enter the generic Revlimid market until January 2026, a delay of 17 years from when it first requested generic Revlimid samples.

377. On September 6, 2017, Celgene filed a patent infringement action against Lotus for filing ANDA No. 210480 for various dosages of its generic Revlimid, which Celgene alleged would infringe its '517 Patent, '720 Patent, '977 Patent, '784 Patent, '740 Patent, '800 Patent, '217 Patent, '569 Patent, '886 Patent, '717 Patent, '498 Patent, '531 Patent, '095 Patent, '120 Patent, '621 Patent, and the '622 Patent.[184]

378. On July 10, 2018, Celgene filed another patent infringement action against Lotus, alleging Lotus's ANDA would also infringe its '357 Patent, '219 Patent, and the '598 Patent.[185] However, Celgene did not submit any of the patents in this case to the Orange Book as required pursuant to 21 U.S.C. §355(b)(1) and attendant FDA regulations. Celgene was required to identify any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use, or sell its drug in its NDA or list any new patents obtained after submission of the NDA within thirty days. Its lawsuit on patents that it failed to list in the Orange Book indicates that Celgene either filed a frivolous infringement claim for a patent that it did not believe could be reasonably asserted or failed to list patents properly, which could give rise to administrative action or potential additional antitrust liability if done to delay filing and further extend its monopoly.

379. Lotus filed answers and counterclaims in all actions, alleging that all of Celgene's asserted patents were invalid, unenforceable, or uninfringed.

380. On August 8, 2018, Celgene filed a Statement informing the court of its covenant not to sue Lotus for infringement of the '217 Patent.[186]

381. On December 17, 2018, the parties submitted a Joint Claim Construction and Prehearing Statement. Lotus argued that the method-of-use patents for multiple myeloma (the

[184] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.,* No. 2:17-cv-06842 (D.N.J.).

[185] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al,* No. 2:18-cv-11518 (D.N.J.).

[186] Statement, *Celgene Corp. v. Lotus Pharm. Co., Ltd., et al.,* No. 2:17-cv-06842, ECF No. 81 (D.N.J. Aug. 8, 2018).

'498, '095, '621, and '622 Patents) were invalid for, among other reasons, indefiniteness of key terms which the parties agreed to address through expert discovery.

382. Invalidation and/or a favorable construction regarding these method-of-use patents, which expire on May 23, 2023, would have paved the way for Lotus and/or other generic rivals to launch a "skinny-label" generic Revlimid only labeled to treat multiple myeloma, thereby endangering Celgene's monopoly.

383. On February 22, 2019, Celgene and Lotus stipulated to bifurcating and staying all proceedings related to the REMS patents (the '720, '977, '784, '886, and '531 Patents), pending Celgene's appeal to the Federal Circuit of the PTAB's invalidation of the '720 Patent (ultimately affirmed on July 30, 2019).

384. On April 1, 2019, Lotus announced a settlement of the patent lawsuits. The terms of the agreement are confidential, but Lotus announced some details in a press release that are largely identical to that announcing the Dr. Reddy's settlement, particularly that Lotus was licensed to sell volume-limited amounts of generic lenalidomide in the United States beginning on a confidential date after March 2022 and without volume limitation starting on January 31, 2026.[187] The "agreed-upon percentages . . . gradually increase each period to no more than a single-digit percentages in the final volume-limited period."[188]

385. Lotus obtained FDA approval for its 5, 10, 15, and 25 mg formulations of generic lenalidomide on August 31, 2022,[189] and launched generic lenalidomide in the approved formulations in the United States in September 2022 (or approximately 180 days/six months after

[187] *Alvogen settles U.S. Revlimid patent litigation with Celgene* (Apr. 1, 2019), *available at* https://www.alvogen.com/newsroom/alvogen-settles-u.s.-revlimid-patent-litigation-with (last visited Aug. 31, 2023).

[188] *Lotus received tentative approval for its ANDA for Lenalidomide from the US FDA* (Sept. 25, 2020), *available at* https://www.lotuspharm.com/newsroom/lotus-received-tentative-approval (last visited Aug. 31, 2023).

[189] *See Generic Revlimid Availability*, Drugs.com (updated on Aug. 9, 2023), *available at https://www.drugs.com/availability/generic-revlimid.html* (last visited Sep. 1, 2023). Lotus did not obtain FDA approval for the 2.5 and 20 mg formulations until March 6, 2023.

Natco launched its generic Revlimid).[190] The date on which Lotus was permitted to launch its formulations of generic Revlimid were ""scheduled according to the settlement agreement" with Celgene.[191]

386. Lotus also did not launch the 2.5 and 20 mg strengths in the United States until Q1 2023 (or approximately 180 days/six months after Dr. Reddy's launched its volume-restricted generic Revlimid in September 2022).[192] Lotus confirmed that the lenalidomide market in the United States is well over $8 billion per year, with Lotus representing to investors that the market was worth over $9 billion in 2019[193] and over $10 billion in 2022.[194] Lotus referred to the launch of generic Revlimid as "the biggest launch in Lotus history so far," and it helped to account for a 245% increase in sales in Q3 of 2022 even with the volume restrictions imposed by

[190] *See Lotus Reports its Best Quarter Ever with the Biggest Launch in its History* (Nov. 10, 2022), *available at https://prismic-io.s3.amazonaws.com/lotus/0fc00afe-57b6-4ed5-ab2b-8dac55d2cd92_Lotus+Reports+Third+Quarter+2022+-+10+NOV+2022_EN_FINAL.pdf*, at 1 (last visited Aug. 31, 2023) and Lotus Third Quarter 2022 Results (Nov. 2022), *available at* https://prismic-io.s3.amazonaws.com/lotus/fcff08f2-78eb-4dc2-8066-9c00dfc13817_Lotus +Q3%2722+ earnings_EN+call_FINAL.pdf, at 5 (last visited Aug. 31, 2023).

[191] Lotus Third Quarter 2022 Results (Nov. 2022),, *available at* https://prismic-io.s3.amazonaws. com/lotus/ fcff08f2-78eb-4dc2-8066-9c00dfc13817_Lotus+Q3%2722+ earnings_EN+call_ FINAL.pdf, at 15 (last visited Aug. 31, 2023).

[192] Lotus 2023 Q1 Earnings Results (May 2023), *available at* https://prismic-io.s3.amazonaws. com/lotus/a5280d47-3767-4e15-a4c8-5f7e6b3625c9_Lotus+Q1%2723+ earnings_ EN+call_0516 Final.pdf, at 5 (last visited Aug. 31, 2023).

[193] Lotus FY2020 Results (Mar. 2021), *available at* https://prismic-io.s3.amazonaws.com/lotus/ 5a4c30f7-778b-4737-afb7-54b4832d2032_Lotus+Q4%2720+earnings_EN+call_ REVISED.pdf, at 11 (last visited Aug. 31, 2023).

[194] Lotus 2023 Q2 Earnings Results (Aug. 2023), *available at https://prismic-io.s3.amazonaws. com/lotus/7808f37f-d01c-42cc-a71d-074db905be84_Lotus+Q2%2723+ earnings_EN+call_0815 Final.pdf*, at 8 (last visited Aug. 31, 2023).

Celgene/BMS.[195] Indeed, Lotus' profits doubled the year after the launch of generic lenalidomide in September 2022.[196]

387. As with Natco and Dr. Reddy's before it, in exchange for ending the patent litigation, Celgene carved out a portion of its monopoly to share with Lotus. It also allocated particular generic competitors into particular sub-markets for generic Revlimid (*i.e.,* the 5/10/15/25 mg and 2.5/20 mg sub-markets).

388. The small volume-limited caps ensure that Lotus has no incentive to compete on price (because, like Natco and Dr. Reddy's, it could benefit from any increased sales resulting from a price reduction). As in the cases of the Natco and Dr. Reddy's settlements, Celgene has no incentive to launch an AG. The net result of the agreement is to limit price competition and preserve Celgene's ability to sell brand Revlimid at monopoly prices. The agreement with Lotus solidified, and was in part induced by, Celgene's agreements with Natco and Dr. Reddy's.

2. Cipla Also Settles Patent Litigation with Celgene and BMS in Exchange for a Slice of the Generic Revlimid Market at Monopoly Pricing Beginning in September 2022

389. As part of its unlawful anticompetitive strategy, Celgene filed four serial patent infringement suits against Cipla USA Inc. ("Cipla"). It brought the actions to delay generic lenalidomide. Cipla's ANDAs are "skinny labels" that seek only to treat multiple myeloma and myelodysplastic syndromes.

390. On August 15, 2017, Celgene filed a patent infringement action against Cipla, for filing ANDA No. 210435 for various dosages of its generic Revlimid, which Celgene alleged would infringe the '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent,

[195] *Lotus Reports its Best Quarter Ever with the Biggest Launch in its History* (Nov. 10, 2022), *available at https://prismic-io.s3.amazonaws.com/lotus/0fc00afe-57b6-4ed5-ab2b-8dac55d2cd92_Lotus+Reports+Third+Quarter+2022+-+10+NOV+2022_EN_FINAL.pdf*, at 1 (last visited Aug. 31, 2023).

[196] *Lotus' revenues grow by 16% and profit double year over year* (Mar. 10, 2023), *available at* https://prismic-io.s3.amazonaws.com/lotus/9d56a958-7ced-4b67-9417-c40037d699ad_Lotus+Reports+4th+Quarter+2022+-+10+Mar+2023_EN_FINAL.pdf, at 1 (last visited Aug 31, 2023).

and the '622 Patent.[197] On May 8, 2018, Celgene filed another patent infringement action against Cipla, alleging Cipla's ANDA would also infringe the '357 Patent, '219 Patent, and the '598 Patent, none of which Celgene listed in the Orange Book as covering Revlimid.[198]

391. On March 29, 2019, Cipla submitted a second ANDA, No. 213165. On July 3, 2019, Celgene filed another patent infringement action against Cipla, alleging Cipla's second ANDA would infringe the '800 Patent, the '217 Patent, the '569 Patent, the '498 Patent, the '095 Patent, the '621 Patent, the '622 Patent, the '740 Patent, the '717 Patent, and the '120 Patent.[199]

392. On May 12, 2020, Cipla submitted a third ANDA, No. 214618. On June 24, 2020, Celgene filed another patent infringement action against Cipla, alleging Cipla's third ANDA would infringe the '800 Patent, the '217 Patent, the '569 Patent, the '498 Patent, the '095 Patent, the '621 Patent, the '622 Patent, the '740 Patent, the '717 Patent, and the '120 Patent.[200]

393. Cipla filed answers and counterclaims in all actions, alleging that all of Celgene's asserted patents were invalid, unenforceable, or uninfringed.

394. On January 14, 2019, the court ordered mediation between the parties. On February 6, 2019, the parties informed the court that *Markman* hearings were no longer necessary.

395. On April 30, 2019, the court issued a stipulated order in which Cipla agreed not to contest that products derived from its ANDA would infringe Celgene's '357, '219, and '598 patents, none of which Celgene listed in the Orange Book as covering Revlimid, while Cipla reserved its rights to argue invalidity.

396. On May 28, 2020, Celgene filed its First Amended Complaint, alleging patent infringement arising from both of Cipla's ANDAs.[201] That day, the parties submitted a Joint

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[197] *Celgene Corp. v. Cipla Ltd.,* No. 2:17-cv-06163 (D.N.J.).

[198] *Celgene Corp. v. Cipla Ltd.,* No. 2:18-cv-08964 (D.N.J.).

[199] *Celgene Corp. v. Cipla Ltd*., No. 2:19-cv-14731 (D.N.J.).

[200] *Celgene Corp. v. Cipla Ltd*., No. 2:20-cv-07759 (D.N.J.).

[201] First Am. Comp., *Celgene Corp. v. Cipla Ltd.,* No. 2:19-cv-14731, ECF No. 64 (D.N.J.).

Claim Construction and Prehearing Statement, informing the court of the absence of disputed terms. On June 8, 2020, Civil Action Nos. 18-08964 and 17-06163 were administratively terminated and incorporated by reference into Civil Action No. 19-14731.

397. On June 22, 2020, the court granted Cipla leave to serve amended noninfringement contentions regarding Celgene's method-of-use patents for multiple myeloma.[202] On July 13, Celgene stipulated to a dismissal of its claims regarding the '217 Patent and filed a covenant not to sue Cipla for infringement of the '217 Patent.[203]

398. On August 21, 2020, Cipla moved for an order compelling Celgene's production of discovery. Celgene's opposition was due September 15, 2020. A telephone conference was scheduled for November 23, 2020.

399. On December 11, 2020, Celgene announced a settlement agreement with Cipla.[204] The terms of the agreement are confidential, but Celgene and Cipla announced some details in a press release that are largely identical to those announcing the Dr. Reddy's and Lotus settlements,[205] indicating a similar settlement with another later-filing generic designed to protect Celgene's monopoly. Specifically, Celgene licensed Cipla to sell volume-limited amounts of generic Revlimid beginning on a confidential date after March 2022 and without volume limitation beginning on January 31, 2026.[206]

[202] Stip. and Order, No. 2:19-cv-14731, ECF No. 67 (D.N.J. June 22, 2020).

[203] Stip. and Order of Dismissal, *Celgene Corp. v. Cipla Ltd.,* No. 2:19-cv-14731, ECF No. 74 (D.N.J. Jul. 13, 2020).

[204] As with the Dr. Reddy's settlement, it is likely that BMS approved Celgene's settlement with Cipla.

[205] *Bristol Myers Squibb Announces Settlement of U.S. Patent Litigation for REVLIMID (lenalidomide) with Cipla* (Dec. 11, 2020), *available at* https://www.businesswire.com/news/home/20201211005052/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-with-Cipla (last visited Sep. 1, 2023).

[206] *Id.*

400. Cipla's earnings calls reveal that, as with Dr. Reddy's and Lotus, Celgene agreed to Cipla launching generic Revlimid on or about September 2022 in "smaller quantity bottles."[207] On November 4, 2022, Cipla's CEO, Umang Vohra, told investors that "the market has been created with everyone who has filed for Revlimid" and acknowledged that Celgene had divvied up the market for generic Revlimid with respect to various formulations.[208]

401. Remarkably, on January 25, 2023, Mr. Vohra told his investors that the Revlimid market "at least for the next one to two years is still going to be a market where the generics would—all generics added together may not possibly be able to satisfy the full demand of Revlimid" and that he was "not sure that there should be intense competition in this segment, despite people getting higher allocations or entering, into the market."[209] Mr. Vohra also advised his investors that generic Revlimid was not "going to behave like a regular generic product at all" in terms of price erosion.[210]

402. In exchange for ending the patent litigation, Celgene carved out a portion of its monopoly to share with Cipla. The volume-limited nature of the license ensures that Cipla has no incentive to compete on price (because, like Natco and Dr. Reddy's, it cannot benefit from any increased sales resulting from a price reduction). As in the Natco, Dr. Reddy's, and Lotus cases, Celgene has no incentive to launch an AG. The net result of the agreement is to limit price

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[207] Cipla Ltd. Q2 FY-22 Earnings Conference Call (Oct 26, 2021), at 17, *available at* https://www.cipla.com/sites/default/files/Earnings-Call-Transcript-Q2FY21.pdf (last visited Sep. 1, 2023); Cipla Q2FY23 Press Release (Nov. 4, 2022), *available at* https://www.cipla.com/sites/default/files/Cipla-Q2FY23-Press-Release.pdf, at 1 (last visited Sep. 1, 2023) (noting that lenalidomide launched in Q2FY2023, which ended November 4, 2023); Cipla Ltd. Q2 FY-23 Earnings Conference Call (Nov. 4, 2022), at 9, *available at* https://www.cipla.com/sites/default/files/Earnings-Call-Transcript-Q2FY23.pdf (last visited Sep. 1, 2023) (stating that Cipla launched lenalidomide in "smaller quantity bottles").

[208] Cipla Ltd. Q2 FY-23 Earnings Conference Call (Nov. 4, 2022), at 9-11, *available at* https://www.cipla.com/sites/default/files/Earnings-Call-Transcript-Q2FY23.pdf (last visited Sep. 1, 2023).

[209] Cipla Ltd. Q3 FY-23 Earnings Conference Call (Jan. 25, 2023), at 9, *available at* https://www.cipla.com/sites/default/files/Earnings-Call-Transcript-Q3FY23.pdf (last visited Sep. 1, 2023).

[210] *Id.* at 15.

competition and preserve Celgene's ability to sell brand Revlimid at monopoly prices. The agreement with Cipla solidified, and was in part induced by, Celgene's agreements with Natco, Dr. Reddy's, and Lotus.

3. Sun Likewise Settles Patent Litigation with Celgene and BMS in Exchange for a Slice of the Generic Revlimid Market at Monopoly Pricing

403. As part of its unlawful anticompetitive strategy, Celgene filed three serial patent infringement suits against Sun Pharmaceutical Industries Ltd. ("Sun"). It brought these actions only to delay generic lenalidomide.

404. In 2018, Sun filed ANDA No. 211846 for generic lenalidomide. Sun's ANDA is a "skinny label" seeking only to treat multiple myeloma. On May 30, 2018, Sun sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Sun's ANDA.

405. On July 13, 2018, Celgene filed a patent infringement action against Sun and related entities for filing its ANDA for various dosages of its generic Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, and '569 Patent.[211]

406. On April 16, 2019, Celgene filed another patent infringement action against Sun, alleging that Sun's ANDA would infringe its '357 Patent, '219 Patent, and its '598 Patent, none of which Celgene listed in the Orange Book as covering Revlimid.[212]

407. On February 2, 2021, Celgene filed yet another patent infringement action against Sun, alleging that Sun's ANDA would infringe its '498 Patent, '095 Patent, '621 Patent, and its '622 Patent.[213]

408. Sun filed answers and counterclaims in the first two actions (the third settled before Sun filed an Answer), alleging that all Celgene's asserted patents were invalid, unenforceable, or uninfringed.

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[211] *Celgene Corp. v. Sun Pharmaceutical Industries, Inc. et al.,* No. 2:18-cv-11630 (D.N.J.).

[212] *Celgene Corp. v. Sun Pharm. Industries, Inc. et al.,* No. 2:19-cv-10099 (D.N.J.).

[213] *Celgene Corp. v. Sun Pharm. Industries, Inc. et al.,* No. 2:21-cv-01734 (D.N.J.).

409. On January 22, 2019, Celgene filed a Statement informing the court of its covenant not to sue Sun for infringement of the '217 Patent.[214]

410. On December 12, 2019, the court cancelled *Markman* hearings upon the parties' joint motion.

411. On June 21, 2021, Sun announced its settlement with Celgene.[215] As with Celgene's other settlement with the later-filed generics, Sun announced that the settlement included a "license to Celgene's patents required to manufacture and sell (subject to USFDA approval) certain limited quantity of generic lenalidomide capsules in the US beginning on a confidential date that is sometime after March 2022" and an "unlimited quantity of generic lenalidomide capsules in the US beginning January 31, 2026."[216]

412. Although the parties have kept the terms of the agreement confidential, Sun launched generic Revlimid in Q4 in fiscal year 2023, or prior to May 26, 2023.[217] During a Sun earnings call that took place on that date, Sun's investors discussed the Generic Revlimid launch, noting that Sun was the "7th or the 8th player to enter" the Revlimid market.[218] Regardless, Sun's launch of generic Revlimid was a "significant contributor" to Sun's 4Q earnings numbers.[219]

413. In exchange for ending the patent litigation, Celgene carved out a portion of its monopoly to share with Sun. The volume-limited nature of the license ensures that Sun has no incentive to compete on price (because, like Natco, it cannot benefit from any increased sales

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[214] Statement, *Celgene Corp. v. Sun Pharm. Industries, Inc*. et al., No. 2:18-cv-11630, ECF No. 50 (D.N.J. Jan. 22, 2019).

[215] *Sun Pharma Announces Settlement of Patent Litigation for Generic Revlimid (lenalidomide) in the US* (Jun. 22, 2021), *available at* https://sunpharma.com/wp-content/uploads/2021/06/Press-Release-Settlement-of-Patent-Litigation-for-Generic-Revlimid-in-US.pdf (last visited Sep. 1, 2023).

[216] *Id.*

[217] Sun Pharma Q4 FY23 Earnings Call Tr. (May 26, 2023), at 6, *available at* https://sunpharma.com/wp-content/uploads/2023/06/FY23-Q4-Earnings-Call-Transcript-1.pdf (last visited Sep. 1, 2023).

[218] *Id.* at 11.

[219] *Id.* at 15.

resulting from a price reduction). As in the Natco, Dr. Reddy's, Lotus, and Cipla cases, Celgene has no incentive to launch an AG. The net result of the agreement is to limit price competition and preserve Celgene's ability to sell brand Revlimid at monopoly prices. The agreement with Sun solidified, and was in part induced by, Celgene's agreements with Natco, Dr. Reddy's, Lotus, and Cipla.

414. On information and belief, Celgene also settled Revlimid patent litigation with Apotex, Aurobindo/Eugia Pharma, Camber/Hetero Labs, Torrent,[220] and Zydus[221] on terms similar to those to those contained in the earlier agreements with Natco, Dr. Reddy, Lotus, Cipla, and Sun.

I. The Reverse Payment Settlement Agreements Have Drastic Anticompetitive Effects on the Revlimid Market to Plaintiffs' Detriment

415. Celgene's and BMS's settlements with the generic manufacturers listed above are a perversion of the Hatch-Waxman Act because they permit Celgene/BMS to pay generic manufacturers not to bring lower-cost alternatives to market and thereby, extend Celgene's fragile patent monopoly.[222]

416. The settlements also result in a large and unjustified transfer of value from Celgene and BMS to the generic manufacturers because the "sham" settlements have artificially allocated the market for generic Revlimid, severely capped generic competition, and awarded settling generic manufacturers with the ability to forestall true generic competition for way

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[220] *See* Ravi, V., *Torrent Settles with BMS for Revlimid, Launch Timeline Undisclosed*, Scrip (Oct. 28, 2021), *available at* https://scrip.pharmaintelligence.informa.com/SC145310/Torrent-Settles-With-BMS-For-Revlimid-Launch-Timeline-Undisclosed (last visited Sep. 1, 2023). According to a May 30, 2023 earnings call, Torrent's settlement agreement with Celgene/BMS put Torrent "in the third batch of people who launch" after October 2023. *Torrent Pharma. Ltd. Q4FY23 Earnings Conf. Call.* (May 30, 2023), *available at* https://www.torrentpharma.com/pdf/investors/Earnings_Call_ Transcript_May_30_2023.pdf, at 5, 9 (last visited Sep. 1, 2023).

[221] *Zydus Announces Settlement of Patent Litigation for Generic Revlimid in U.S.* (Mar. 24, 2021), *available at* https://zyduslife.com/public/pdf/pressrelease/Zydus_Announces_Settlement_of_Patent_Litigation_for_Generic_Revlimid_in_US.pdf (last visited Sep. 1, 2023).

beyond the 180 days that would have been granted had they launched as first-filers under the Hatch-Waxman Act.

1. The Anticompetitive Effects of Celgene's and BMS's Reverse Payments to Natco, Teva, and Dr. Reddy's

417. As noted above, a reverse payment in the form of a no-AG agreement is worse than a cash payment because it delays generic entry and maintains higher generic prices after generic entry, typically for six months, while a cash payment simply delays generic entry. No-AG agreements "can be viewed as a form of market diversion, with the generic company agreeing to delay entering the market (prolonging the brand's monopoly) and the brand company agreeing not to introduce an AG during the first-filing generic's exclusivity period, creating a generic monopoly."[223]

418. The volume-limited license agreements that Celgene entered into with Natco, Dr. Reddy's, and the later-filing generics are even more anticompetitive than a no-AG agreement in two significant respects. First, since a seller with a volume limit has no incentive to lower prices, these agreements ensured that generic Revlimid would be priced very close to the brand price from March 2022 through January 2026. The current prices for Branded and Generic Revlimid are reflected below:

[223] Jones, G., Carrier, M., Silver, R., and Kantarjian, H., *Strategies that delay or prevent the timely availability of affordable generic drugs in the United States*, Blood (Mar. 17, 2016), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915805/ (last visited Aug. 29, 2023). ("Unfortunately, the [Hatch-Waxman Act] has been exploited by brand and generic companies that mutually benefit from [pay-for-delay] settlement, as the brand company can pay the generic company to extend its patent monopoly, while the generic company receives guaranteed compensation.").

Strength	Brand Revlimid[224]	Generic Revlimid[225]	Discount	Discount in a Competitive Market	Resulting Price in a Competitive Market
2.5 mg	$805.10	$605.19	25%	70%	$241.53
5 mg	$805.10	$605.19	25%	70%	$241.53
10 mg	$805.10	$525.19	35%	70%	$241.53
15 mg	$805.10	$555.19	31%	70%	$241.53
20 mg	$805.10	$605.19	25%	70%	$241.53
25 mg	$805.10	$605.19	25%	70%	$241.53

419. Second, the volume-limited license agreements have artificially capped and will continue to artificially cap the generic market share at much lower levels than would be expected under normal competitive conditions. By contrast, a no-AG agreement has virtually no effect on generic penetration, and its effect on generic prices typically lasts only six months. In other words, a no-AG clause keeps the generic price artificially high for six months, while the Revlimid market-division scheme will keep generic prices substantially higher, and generic substitution artificially lower, for almost four years.

420. Celgene continued to file patent infringement litigation against any generic Revlimid ANDA filer. Celgene and the later-filing generics have kept all the terms of their settlement agreements confidential, to the point that later-filing generics have been hampered in their presentations to their own investors about the terms of the settlement agreements.

421. Celgene and BMS's scheme was intended to and did in fact block and delay generic lenalidomide entry into the market. It destroyed incentives for price competition, disrupted the normal distribution channels, and manipulated the statutory and regulatory

[224] Pricing here is derived from prices listed on drugs.com and then divided for a per-capsule amount. Revlimid is generally prescribed in either a 21-day or 28-day dose. *See* Revlimid Price Guide, drugs.com, *available at* https://www.drugs.com/price-guide/revlimid (last visited Sep. 13, 2023).

[225] Pricing here is derived from utilizing the lowest (*i.e.* most conservative) listed price on WellRx for the Trenton, NJ area and divided for a per-capsule amount. *See* Lenalidomide (Generic for Revlimid), WellRx, *available at* https://www.wellrx.com/prescriptions/revlimid/08601/?isModSearch=true (last visited Sep. 13, 2023).

mechanisms by which generic competition takes place, and otherwise excluded generic competitors from competitively marketing and distributing their products.

422. The Revlimid reverse payment, output-restriction and market-allocation agreement will prevent true generic competition for Revlimid until at least January 31, 2026. As a result, Plaintiffs have been and will continue to be forced to purchase brand Revlimid at supra-competitive prices through at least early 2026. Plaintiffs have also paid and will continue to pay supracompetitive prices for generic Revlimid until at least January 31, 2026.

423. Absent Defendants' unlawful conspiracy, generic Revlimid would have been available—and on a much wider scale—prior to March 2022, on an exact date to be established during discovery.

424. Such entry would have occurred because, absent the unlawful payment scheme, a reasonable generic company in the position of Natco/Teva or Dr. Reddy's would have: (i) launched generic Revlimid after prevailing at trial; (ii) launched at risk; or (iii) entered into a payment-free agreement that provided for an earlier agreed entry date. Celgene would have launched an AG simultaneously with the launch of the first generic and additional generic competitors would have launched six months later. Plaintiffs would have substituted lower-priced generic Revlimid for higher-priced branded Revlimid at the time of generic entry and would have paid lower prices for the generic Revlimid they were belatedly permitted to purchase, in limited volumes, starting in March 2022.

425. Absent Defendants' unlawful conduct, Plaintiffs would have paid less for lenalidomide by substituting purchases of less expensive AB-rated generic Revlimid for purchases of more expensive branded Revlimid, by paying lower prices for the limited volume of generic Revlimid they have been allowed to purchase since March 2022, and by purchasing generic versions of Revlimid at lower prices sooner.

426. A 2010 study by the FTC found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%, findings that have been confirmed by later studies. Given that there were multiple generic filers for Revlimid, it is likely that additional generics would have

entered subsequent to Natco/Teva, driving down prices further in a working market.[226] In the absence of a truly competitive market, Plaintiffs have sustained and will continue to sustain substantial loss and injury to their business and property in the form of overcharges on Revlimid purchases through at least early 2026, the exact amount of which will be the subject of proof at trial.

2. The Reverse Payments from Celgene and BMS to Natco, Teva, and Dr. Reddy's Were Both Large and Unjustified

427. The reverse payments here took the form of volume-limited, royalty-free licenses that began in March 2022 and MFEP clauses that guaranteed Natco/Teva a limited share of the 5, 10, 15, and 25 mg Revlimid market and Dr. Reddy's a limited share of the 2.5 and 20 mg Revlimid market at prices close to the price of branded Revlimid.

428. A seller with a volume limit has no incentive to compete on price. Adding generic sellers with volume limits will put no downward pressure on price.

429. As detailed above, Celgene's and BMS's settlement agreements with Natco/Teva, and later Dr. Reddy's, provided for volume-limited, royalty-free licenses. During Natco's February 12, 2016 earnings call (held shortly after the Revlimid settlement with Celgene was announced), Natco's CEO, Rajeev Nannapaneni, explained to investors: "We have a launch date [for Revlimid]. The launch date is clear. It allows us to launch *without paying a license fee* that is the arrangement that we have."[227] On information and belief, BMS's settlement with Dr. Reddy's similarly provided for volume-limited, royalty-free licenses, only for a different formulations of Revlimid.

430. The volume-limited, royalty-free licenses granted to both Natco/Teva and Dr. Reddy's effectively operate as a side deal whereby the brand manufacturer compensates the

[226] *See* R. Conrad and R. Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices*, FDA: Generic Competition and Drug Prices (December 2019), available at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices (last visited Aug. 20, 2023).

[227] *Natco Pharma Q3 FY 2016 Earnings Conference Call* (Feb. 12, 2016), *available at* https://natcopharma.co.in/wp-content/uploads/2016/02/NirmalBang-NatcoPharma-Feb12-2016.pdf (last visited Aug. 30, 2023) (emphasis added).

generic manufacturer by guaranteeing sales at a generic price very close to the branded price, regardless of the number of generics in the market. Here, Natco/Teva and Celgene agreed that Natco/Teva would be allowed to capture 7% of the multi-billion-dollar Revlimid market at prices close to the price of branded Revlimid for the 5, 10, 15, and 25 mg strengths, and, on information and belief, Dr. Reddy's would be allowed to capture 7% of the multi-billion-dollar Revlimid market at prices close to the price of branded Revlimid for the 2.5 and 20 mg strengths.

431. Although the precise value of the reverse payments to Natco/Teva and Dr. Reddy's (the royalty-free license + use of Celgene's REMS system + the escalating volume-limited market share + the ability to charge monopoly pricing for longer than the 180-day period of the Hatch Waxman Act exclusivity) are, without the benefit of discovery, unknown, they *far* exceed the costs that would have been incurred by Natco/Teva and Dr. Reddy's in patent litigation and they outweigh the profit margins Natco/Teva and Dr. Reddy's would have realized had either prevailed in patent litigation (which would have resulted, in a competitive market, in price competition with Celgene's AG during the 180-day period of the Hatch-Waxman Act exclusivity and full-fledged generic competition thereafter).

432. The median patent litigation costs for Hatch-Waxman Act/ANDA patent litigation matters with more than $25 million potentially at stake are approximately $5 to $6 million.[228]

433. In a July 2019 filing with the SEC, Celgene reported that net Revlimid sales were approximately $2.5 billion per quarter globally (or $10 billion annually) and $1.8 billion per quarter in the United States (or $7.2 billion annually).[229]

434. Seven percent of an approximately $7.2 billion market is approximately $504 million per year or, roughly 100 times the cost of patent litigation.

[228] *See* AIPLA Report of the Economic Survey 2019 at 51, *available at* https://www.aipla.org/home/news-publications/economic-survey.

[229] *Celgene Reports Second Quarter 2019 Operating and Financial Results*, Ex-99.1, *available at* https://www.sec.gov/Archives/edgar/data/816284/000110465919042485/a19-13289_1ex99d1.htm#:~:text=Net%20Product%20Sales%20Performance&text=REVLIMID%C2%AE%20sales%20for%20the,%2Dover%2Dyear%2C%20respectively (last visited Oct. 3, 2023).

435. Even accounting for the fact that Natco/Teva and Dr. Reddy's would charge an amount for Revlimid lower than Celgene and BMS, would only capture a certain percentage of sales, and would have to account for the cost of manufacturing and sales, the reverse payment still dwarfs the amount Natco/Teva and/or Dr. Reddy's would have spent invalidating Celgene's patent fortress.

436. It also far outweighs the profit Natco/Teva and Dr. Reddy's would have realized in a competitive market had either successfully invalidated Celgene's Revlimid patents. Had either done so, they would have had to compete with Celgene and BMS during their 180-day exclusivity period under the Hatch-Waxman Act, which would significantly cut into their profits. Under their settlement agreements with Celgene and BMS, Natco/Teva and Dr. Reddy's were free from competition from an AG and, thus, could maintain a higher market share at higher prices during the first 180 days of their sales period.

437. After those initial 180 days (6 months), Natco/Teva and Dr. Reddy's would have faced full-fledged generic competition, which would have driven the price of generic Revlimid down significantly and forced each to expend resources to maintain market share. Their anticompetitive settlement agreements with Celgene and BMS, on the other hand, insulated them from any generic competition for a period of roughly 46 months—from March 2022 until January 2026—and gifted them a guaranteed share of the Revlimid market for a defined period of time. Neither Natco/Teva nor Dr. Reddy's had to expend any resources to obtain and/or maintain this market share. And, as demonstrated above, it allowed both Natco/Teva and Dr. Reddy's to charge at least 35 to 45% more for generic Revlimid in their respective doses than they could have if subjected to competition for those 46 months. Based on the current prices for generic Revlimid, Natco/Teva and Dr. Reddy's are each making approximately $8,000-$10,000 more for *every single* 28-day generic Revlimid prescription than they would have in a competitive market. Given the sales volume for Revlimid, this reflects a significant deviation from the profits Natco/Teva and Dr. Reddy's would have realized absent these anticompetitive agreements.

438. Moreover, the fact that Celgene and BMS were willing to concede over $500 million per year of their own United States Revlimid revenue to generic manufacturers for a four-

year period—or roughly $2 billion in revenue—further supports the large and unjustified nature of the settlement agreements with both Natco/Teva and Dr. Reddy's. Two billion dollars exceeds the amount Celgene and BMS would have spent on even 20 of the most contentious Revlimid patent infringement lawsuits. But the consequences of losing even one of those patent infringement suits would have simply been too high for both Celgene and BMS, putting at risk a roughly $7 billion per year enterprise built on fragile and fraudulently-obtained patents.

439. Instead, Celgene and BMS orchestrated, in concert with Natco/Teva and later Dr. Reddy's, a series of reverse payment, output-restriction and market-allocation agreements that will continue to prevent true generic competition for Revlimid until at least January 31, 2026. As a result, Plaintiffs have been and will continue to be forced to purchase brand Revlimid at supra-competitive prices through at least early 2026. Plaintiffs have also paid and will continue to pay supracompetitive prices for generic Revlimid until at least January 31, 2026.

VI. TRADE AND COMMERCE

440. Revlimid is sold in interstate commerce, and the unlawful activities alleged herein have substantially affected interstate commerce.

VII. MARKET EFFECTS

441. At all relevant times, Celgene (joined later by BMS) had monopoly power over the market for Revlimid in all its forms and dosages, even after the launch of generic Revlimid in March 2022. Celgene has and continues to have the power to maintain and increase the price of Revlimid to supracompetitive levels without losing sales.

442. A small, but significant, non-transitory price increase on Revlimid by Celgene and BMS would not have caused a significant loss of sales.

443. Celgene needed to control only Revlimid and its AB-rated generic equivalents, and no other products, to maintain the price of Revlimid at supracompetitive prices. As detailed above, Celgene's executives understood that Celgene had this power. They believed that they could raise the price of Revlimid "any time they wanted." Only the unrestricted market entry of a

competing AB-rated generic version of those drugs would render Celgene unable to maintain its market monopoly.

444. The relevant product market consists of all strengths of lenalidomide, *i.e.*, Revlimid and its AB-rated generic equivalents.

445. Revlimid does not exhibit significant, positive cross-elasticity of demand regarding price with any other product, due to FDA regulatory hurdles incident to securing an AB rating and laws allowing pharmacists to substitute only AB-rated generics for prescribed branded drugs.

446. There are no interchangeable drug products available for purchasers of Revlimid.

447. Other drugs that are not AB-rated to Revlimid cannot be substituted automatically for Revlimid by pharmacists, do not exhibit substantial cross-price elasticity of demand with Revlimid, and thus are not economic substitutes for, nor reasonably interchangeable with, Revlimid.

448. The existence of other products designed to treat the conditions treated by Revlimid have not constrained Celgene's and BMS's pricing of Revlimid to the competitive level. Celgene and BMS have never lowered the price of Revlimid in response to the pricing of other branded or generic drugs.

449. Celgene and BMS needed to control only the sales of Revlimid and its generic equivalents, and no other products, in order to maintain the price of Revlimid profitably at supracompetitive prices. Only the unrestrained market entry of an AB-rated generic version of Revlimid would render Celgene and BMS unable to profitably maintain prices of Revlimid at current levels without losing substantial sales.

450. Celgene's and BMS's reverse payment to Natco and Teva demonstrate that Celgene and BMS enjoyed monopoly power in the relevant market.

451. Celgene also sold branded Revlimid at prices well above marginal costs, and substantially more than the competitive price, and enjoyed unusually high profit margins.

452. Celgene has had, and so exercised, the power to exclude and restrict competition for Revlimid.

453. Without the power to exclude and restrict competition for Revlimid, and the ability to sell its own branded version of those drugs at prices well over marginal costs, it would not have been economically rational for Celgene to make exorbitant payments to settle with Natco or Dr. Reddy's (and potentially others) to delay the launch of generic Revlimid.

454. At all relevant times, Celgene (later joined by BMS) has enjoyed the benefits of high barriers to entry with respect to competition in the above-defined market due to patent and other regulatory protections.

455. At all times before March 2022, Celgene and BMS possessed a 100% share of the relevant market, indicating substantial monopoly power. They continue to possess an overwhelming share of the relevant market today.

456. The relevant geographic market is the United States and its territories.

VIII. ANTITRUST IMPACT AND INJURY

457. Defendants' unlawful conduct injured Plaintiffs by forcing them to pay higher prices for their requirements of branded and generic lenalidomide than they would have paid in the absence of that conduct.

458. Plaintiffs paid substantial sums to purchase Revlimid during the relevant time period at prices substantially higher than the prices Plaintiffs would have paid for the drug in the absence of the illegal conduct. Plaintiffs continue to pay artificially high, supracompetitive prices for Revlimid as a direct and proximate result of Defendants' anticompetitive conduct.

459. Prices for Revlimid and generic Revlimid have been and will continue to be inflated as a direct and foreseeable result of Defendants' anticompetitive conduct. Defendants' unlawful conduct will continue to force Plaintiffs and other purchasers to pay higher prices for the drug until at least January 2026.

460. The overcharges that Plaintiffs have paid and will continue to pay are injury of the type the antitrust laws were designed to prevent and flow from that which makes Defendants' conduct unlawful.

IX. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
CONSPIRACY IN RESTRAINT OF TRADE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT
(Against Defendants Celgene, BMS, and Natco/Teva)

461. Plaintiffs repeat and reallege every preceding allegation as if fully set forth herein.

462. Beginning in 2015, and continuing through the present day, Defendants have entered into a continuing unlawful contract, combination and conspiracy in violation of section 1 of the Sherman Act, 15 U.S.C. § 1. Specifically, Celgene, BMS, and Natco/Teva entered into an unlawful horizontal agreement to restrict output and allocate the Revlimid market beginning in March 2022, thereby transferring billions of dollars in value to Natco/Teva in return for Natco/Teva's agreement to delay the launch of its AB-rated generic Revlimid in the 5, 10, 15, and 25 mg strengths until on or about March 1, 2022.

463. Defendants' settlement agreement constitutes a horizontal output-restriction and market-allocation agreement—a *per se* violation of the Sherman Act.

464. In the alternative, Defendants' unlawful agreement substantially harmed competition in the relevant market by delaying the availability of less expensive generic Revlimid in the 5, 10, 15, and 25 mg strengths, artificially maintaining the price of Revlimid at supracompetitive levels and artificially maintaining the price of generic Revlimid at supracompetitive levels.

465. Defendants' unlawful conspiracy (a) allocated to Celgene and BMS 100% of the U.S. sales of lenalidomide at the 5, 10, 15, and 25 mg strengths from at least 2019 until March 2022; (b) delayed the availability of generic lenalidomide in the 5, 10, 15, and 25 mg strengths from at least 2019 until March 2022; (c) allocated 7% of the Revlimid market to Natco/Teva from March 2022 until at least February 2023; (d) allocated unknown percentages of the Revlimid market to Natco/Teva from February 2023 through January 31, 2026; (e) restricted the output of generic lenalidomide from at least 2019 until January 31, 2026; (f) ensured that generic prices would remain artificially high, and generic substitution artificially low, from March 2022 until January 20, 2026; and (g) fixed and maintained, at supracompetitive levels, and will continue to

fix and maintain at supracompetitive levels, the price Plaintiffs paid for lenalidomide from at least 2019 until January 30, 2026.

466. As a result of Defendants' unlawful conduct, Plaintiffs have been forced to pay overcharges on their purchases of branded and generic Revlimid.

467. There was and is no legitimate, non-pretextual, pro-competitive justification for this reverse payment agreement that outweighs its harmful effect on competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose.

468. The anticompetitive effects of Defendants' reverse-payment agreement agreements continue to this day and will continue through at least January 2026.

469. As a direct result of Celgene's and BMS' unlawful monopolization, Plaintiffs have suffered and will continue to suffer injury to their business and property in the form of overcharges.

SECOND CLAIM FOR RELIEF
CONSPIRACY IN RESTRAINT OF TRADE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT
(Against Defendants Celgene, BMS, and Dr. Reddy's)

470. Plaintiffs repeat and reallege every preceding allegation as if fully set forth herein.

471. Beginning in 2020, and continuing through the present day, Defendants have entered into a continuing unlawful contract, combination and conspiracy in violation of section 1 of the Sherman Act, 15 U.S.C. § 1. Specifically, Celgene, BMS, and Dr. Reddy's entered into an unlawful horizontal agreement to restrict output and allocate the Revlimid market beginning in September 2022, thereby transferring billions of dollars in value to Dr. Reddy's in return for Dr. Reddy's agreement to delay the launch of its AB-rated generic Revlimid in the 2.5 and 20 mg strengths until September 1, 2022.

472. Defendants' settlement agreement constitutes a horizontal output-restriction and market-allocation agreement—a *per se* violation of the Sherman Act.

473. In the alternative, Defendants' unlawful agreement substantially harmed competition in the relevant market by delaying the availability of less expensive generic Revlimid

in the 2.5 and 20 mg strengths, artificially maintaining the price of Revlimid at supracompetitive levels and artificially maintaining the price of generic Revlimid at supracompetitive levels.

474. Defendants' unlawful conspiracy (a) allocated to Celgene and BMS 100% of the U.S. sales of lenalidomide at the 2.5 and 20 mg strengths from at least 2019 until September 2022; (b) delayed the availability of generic lenalidomide in the 2.5 and 20 mg strengths from at least 2019 until September 2022; (c) allocated 7% of the Revlimid market to Dr. Reddy's from September 2022 until at least March 2023; (d) allocated unknown percentages of the Revlimid market to Dr. Reddy's from March 2023 through January 31, 2026; (e) restricted the output of generic lenalidomide from at least 2019 until January 31, 2026; (f) ensured that generic prices would remain artificially high, and generic substitution artificially low, from September 2022 until January 20, 2026; and (g) fixed and maintained, at supracompetitive levels, and will continue to fix and maintain at supracompetitive levels, the price Plaintiffs paid for lenalidomide from at least 2019 until January 30, 2026.

475. As a result of Defendants' unlawful conduct, Plaintiffs have been forced to pay overcharges on their purchases of branded and generic Revlimid.

476. There was and is no legitimate, non-pretextual, pro-competitive justification for this reverse payment agreement that outweighs its harmful effect on competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose.

477. The anticompetitive effects of Defendants' reverse-payment agreement agreements continue to this day and will continue through at least January 2026.

478. As a direct result of Celgene's and BMS' unlawful monopolization, Plaintiffs have suffered and will continue to suffer injury to their business and property in the form of overcharges.

THIRD CLAIM FOR RELIEF
MONOPOLIZATION IN VIOLATION OF
SECTION 2 OF THE SHERMAN ACT
(Against Defendants Celgene and BMS)

479. Plaintiffs repeat and reallege every preceding allegation as if fully set forth herein.

480. At all relevant times, Celgene and BMS have enjoyed monopoly power in the relevant market. That monopoly power will continue to exist until at least January 31, 2026.

481. Celgene and BMS have knowingly and willfully maintained their monopoly power in the relevant market by a course of conduct that has prevented generic manufacturers from launching AB-rated generic versions of Revlimid and by colluding with actual or potential generic competitors to suppress and delay generic competition. This course of conduct has included: (a) refusing to sell or otherwise provide samples of Revlimid to generic manufacturers; (b) fraudulently procuring patents; (c) abusing the REMS process; (d) abusing the citizen petition process; (e) improperly and serially filing and prosecuting patent infringement actions against generic manufacturers without regard to their merit or likely outcome; and (f) entering into the reverse payment/horizontal output-restriction and market-allocation agreements described above. Celgene's and BMS's conduct amounts to unlawful monopolization proscribed by section 2 of the Sherman Act, 15 U.S.C. § 2.

482. Celgene and BMS have maintained their monopoly power by colluding with and excluding competitors, and not from growth or development resulting from a superior product, business acumen, or historic accident.

483. Celgene's and BMS's unlawful monopolization (a) allocated to Celgene and BMS 100% of the U.S. sales of lenalidomide from at least 2019 until March 2022; (b) delayed the availability of generic lenalidomide from at least 2019 until March 2022; (c) allocated 7% of the Revlimid market to Natco and Teva in the 5, 10, 15, and 25 mg strengths from March 2022 until February 2023; (d) allocated unknown percentages of the Revlimid market in the 5, 10, 15, and 25 mg strengths to Natco and Teva from February 2023 through January 31, 2026; (e) allocated 7% of the Revlimid market to Dr. Reddy's in the 2.5 and 20 mg strengths from September 2022 until at least March 2023; (f) allocated unknown percentages of the Revlimid market in the 2.5 and 20 mg strengths to Dr. Reddy's after March 2023; (g) allocated unknown percentages of the Revlimid market to certain later-filing generics beginning in September 2022 and continuing until January 31, 2026; (f) restricted the output of generic lenalidomide from at least 2019 until January 31, 2026; (g) ensured that generic prices would remain artificially high, and generic

substitution artificially low, from March 2022 until January 20, 2026; and (h) fixed and maintained, at supracompetitive levels, and will continue to fix and maintain at supracompetitive levels, the price Plaintiffs paid for lenalidomide from at least 2019 until January 30, 2026.

484. The goal, purpose and effect of the conduct alleged herein was to maintain, enhance, and extend Celgene's and BMS's monopoly power, in violation of Sherman Act Section 2, 15 U.S.C. § 2.

485. Defendants Celgene and BMS knowingly and intentionally maintained, enhanced, and extended their monopoly power in the relevant market.

486. As a result of Celgene's and BMS's unlawful conduct, Plaintiffs have been forced to pay overcharges on their purchases of branded and generic Revlimid.

487. The anticompetitive effects of Celgene's and BMS's unlawful monopolization continue to this day and will continue through at least January 2026.

488. As a direct result of Celgene's and BMS' unlawful monopolization, Plaintiffs have suffered and will continue to suffer injury to their business and property in the form of overcharges.

FOURTH CLAIM FOR RELIEF
CONSPIRACY IN RESTRAINT OF TRADE
IN VIOLATION OF STATE LAW
(Against Defendants Celgene, BMS, and Natco/Teva)

489. Plaintiffs repeat and reallege every preceding allegation as if fully set forth herein.

490. Beginning in 2015, and continuing through the present day, Defendants have entered into a continuing unlawful contract, combination and conspiracy in violation of the state laws outlined below. Specifically, Celgene, BMS, and Natco/Teva entered into an unlawful horizontal agreement to restrict output and allocate the Revlimid market beginning in March 2022, thereby transferring billions of dollars in value to Natco/Teva in return for Natco/Teva's agreement to delay the launch of its AB-rated generic Revlimid in the 5, 10, 15, and 25 mg strengths until on or about March 1, 2022.

491. Defendants' settlement agreement constitutes a horizontal output-restriction and market-allocation agreement—a *per se* violation of the state laws outlined below.

492. In the alternative, Defendants' unlawful agreement substantially harmed competition in the relevant market by delaying the availability of less expensive generic Revlimid in the 5, 10, 15, and 25 mg strengths, artificially maintaining the price of Revlimid at supracompetitive levels and artificially maintaining the price of generic Revlimid at supracompetitive levels.

493. Defendants' unlawful conspiracy (a) allocated to Celgene and BMS 100% of the U.S. sales of lenalidomide from at least 2019 until March 2022; (b) delayed the availability of generic lenalidomide in the 5, 10, 15, and 25 mg strengths from at least 2019 until March 2022; (c) allocated 7% of the Revlimid market in the 5, 10, 15, and 25 mg strengths to Natco/Teva from March 2022 until at least February 2023; (d) allocated unknown percentages of the Revlimid market to Natco and Teva from February 2023 through January 31, 2026; (e) restricted the output of generic lenalidomide from at least 2019 until January 31, 2026; (f) ensured that generic prices would remain artificially high, and generic substitution artificially low, from March 2022 until January 20, 2026; and (g) fixed and maintained, at supracompetitive levels, and will continue to fix and maintain at supracompetitive levels, the price Plaintiffs paid for lenalidomide from at least 2019 until January 30, 2026.

494. As a result of Defendants' unlawful conduct, Plaintiffs have been forced to pay overcharges on their purchases of branded and generic Revlimid.

495. There was and is no legitimate, non-pretextual, pro-competitive justification for this reverse payment agreement that outweighs its harmful effect on competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose.

496. The anticompetitive effects of Defendants' reverse-payment agreement agreements continue to this day and will continue through at least January 2026.

497. By engaging in the foregoing conduct, Defendants intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

Jurisdiction	Relevant Statute(s)
Arizona	Ariz. Rev. Stat., § 44-1401, *et seq.*
California	Cal. Bus. & Prof. Code §16700, *et seq.*
Illinois	740 Ill. Comp. Stat. 10/1, *et seq.*
Iowa	Iowa Code § 553.1, *et seq.*
Kansas	Kan. Stat. Ann. § 50-101, *et seq.*
Michigan	Mich. Comp. Laws § 445.771, *et seq.*
Minnesota	Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*
Nevada	Nev. Rev. Stat. § 598A.010, *et seq.*
New Mexico	N.M. Stat. Ann. § 57-1-1, *et seq.*
North Carolina	N.C. Gen. Stat. § 75-1, *et seq.*
Oregon	Or. Rev. Stat. § 646.705, *et seq.*
Rhode Island	R.I. Gen. Laws § 6-36-1, *et seq.*
Tennessee	Tenn. Code § 47-25-101, *et seq.*
Utah	Utah Code Ann. §§ 76-10-3101, *et seq.*
West Virginia	W. Va. Code § 47-18-1, *et seq.*
Wisconsin	Wisc. Stat. § 133.01, *et seq.*

FIFTH CLAIM FOR RELIEF
CONSPIRACY IN RESTRAINT OF TRADE
IN VIOLATION OF STATE LAW
(Against Defendants Celgene, BMS, and Dr. Reddy's)

498. Plaintiffs repeat and reallege every preceding allegation as if fully set forth herein.

499. Beginning in 2020, and continuing through the present day, Defendants have entered into a continuing unlawful contract, combination and conspiracy in violation of the state laws outlined below. Specifically, Celgene, BMS, and Dr. Reddy's entered into an unlawful horizontal agreement to restrict output and allocate the Revlimid market beginning in September 2022, thereby transferring billions of dollars in value to Dr. Reddy's in return for Dr. Reddy's agreement to delay the launch of its AB-rated generic Revlimid in the 2.5 and 20 mg strengths until September 1, 2022.

500. Defendants' settlement agreement constitutes a horizontal output-restriction and market-allocation agreement—a *per se* violation of the state laws outlined below.

501. In the alternative, Defendants' unlawful agreement substantially harmed competition in the relevant market by delaying the availability of less expensive generic Revlimid in the 2.5 and 20 mg strengths, artificially maintaining the price of Revlimid at supracompetitive levels and artificially maintaining the price of generic Revlimid at supracompetitive levels.

502. Defendants' unlawful conspiracy (a) allocated to Celgene and BMS 100% of the U.S. sales of lenalidomide from at least 2019 until September 2022; (b) delayed the availability of generic lenalidomide in the 2.5 and 20 mg strengths from at least 2019 until September 2022; (c) allocated 7% of the Revlimid market to Dr. Reddy's from September 2022 until at least March 2023; (d) allocated unknown percentages of the Revlimid market to Dr. Reddy's from March 2023 through January 31, 2026; (e) restricted the output of generic lenalidomide from at least 2019 until January 31, 2026; (f) ensured that generic prices would remain artificially high, and generic substitution artificially low, from September 2022 until January 20, 2026; and (g) fixed and maintained, at supracompetitive levels, and will continue to fix and maintain at supracompetitive levels, the price Plaintiffs paid for lenalidomide from at least 2019 until January 30, 2026.

503. As a result of Defendants' unlawful conduct, Plaintiffs have been forced to pay overcharges on their purchases of branded and generic Revlimid.

504. There was and is no legitimate, non-pretextual, pro-competitive justification for this reverse payment agreement that outweighs its harmful effect on competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve the purpose.

505. The anticompetitive effects of Defendants' reverse-payment agreement agreements continue to this day and will continue through at least January 2026.

506. By engaging in the foregoing conduct, Defendants intentionally and wrongfully engaged in a contract, combination, or conspiracy in restraint of trade in violation of the following state antitrust laws:

Jurisdiction	**Relevant Statute(s)**
Arizona	Ariz. Rev. Stat., § 44-1401, *et seq.*
California	Cal. Bus. & Prof. Code §16700, *et seq.*
Illinois	740 Ill. Comp. Stat. 10/1, *et seq.*
Iowa	Iowa Code § 553.1, *et seq.*
Kansas	Kan. Stat. Ann. § 50-101, *et seq.*
Michigan	Mich. Comp. Laws § 445.771, *et seq.*
Minnesota	Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*
Nevada	Nev. Rev. Stat. § 598A.010, *et seq.*

New Mexico	N.M. Stat. Ann. § 57-1-1, *et seq.*
North Carolina	N.C. Gen. Stat. § 75-1, *et seq.*
Oregon	Or. Rev. Stat. § 646.705, *et seq.*
Rhode Island	R.I. Gen. Laws § 6-36-1, *et seq.*
Tennessee	Tenn. Code § 47-25-101, *et seq.*
Utah	Utah Code Ann. §§ 76-10-3101, *et seq.*
West Virginia	W. Va. Code § 47-18-1, *et seq.*
Wisconsin	Wisc. Stat. § 133.01, *et seq.*

SIXTH CLAIM FOR RELIEF
MONOPOLIZATION IN VIOLATION OF STATE LAW
(Against Defendants Celgene and BMS)

507. Plaintiffs repeat and reallege every preceding allegation as if fully set forth herein.

508. At all relevant times, Celgene and BMS have enjoyed monopoly power in the relevant market. That monopoly power will continue to exist until at least January 31, 2026.

509. Celgene and BMS have knowingly and willfully maintained their monopoly power in the relevant market by a course of conduct that has prevented generic manufacturers from launching AB-rated generic versions of Revlimid and by colluding with actual or potential generic competitors to suppress and delay generic competition. This course of conduct has included: (a) refusing to sell or otherwise provide samples of Revlimid to generic manufacturers; (b) fraudulently procuring patents; (c) abusing the REMS process; (d) abusing the citizen petition process; (e) improperly and serially filing and prosecuting patent infringement actions against generic manufacturers without regard to their merit or likely outcome; and (f) entering into the reverse payment/horizontal output-restriction and market-allocation agreements described above. Celgene's and BMS's conduct amounts to unlawful monopolization proscribed by the state statutes listed below.

510. Celgene and BMS have maintained their monopoly power by colluding with and excluding competitors, and not from growth or development resulting from a superior product, business acumen, or historic accident.

511. Celgene's and BMS's unlawful monopolization (a) allocated to Celgene and BMS 100% of the U.S. sales of lenalidomide from at least 2019 until March 2022; (b) delayed the availability of generic lenalidomide from at least 2019 until March 2022; (c) allocated 7% of the

Revlimid market to Natco and Teva in the 5, 10, 15, and 25 mg strengths from March 2022 until February 2023; (d) allocated unknown percentages of the Revlimid market in the 5, 10, 15, and 25 mg strengths to Natco and Teva from February 2023 through January 31, 2026; (e) allocated 7% of the Revlimid market to Dr. Reddy's in the 2.5 and 20 mg strengths from September 2022 until at least March 2023; (f) allocated unknown percentages of the Revlimid market in the 2.5 and 20 mg strengths to Dr. Reddy's after March 2023; (g) allocated unknown percentages of the Revlimid market to certain later-filing generics beginning in September 2022 and continuing until January 31, 2026; (f) restricted the output of generic lenalidomide from at least 2019 until January 31, 2026; (g) ensured that generic prices would remain artificially high, and generic substitution artificially low, from March 2022 until January 20, 2026; and (h) fixed and maintained, at supracompetitive levels, and will continue to fix and maintain at supracompetitive levels, the price Plaintiffs paid for lenalidomide from at least 2019 until January 30, 2026.

512. The goal, purpose and effect of the conduct alleged herein was to maintain, enhance, and extend Celgene's and BMS's monopoly power, in violation of the state statutes listed below.

513. Defendants Celgene and BMS knowingly and intentionally maintained, enhanced, and extended their monopoly power in the relevant market.

514. As a result of Celgene's and BMS's unlawful conduct, Plaintiffs have been forced to pay overcharges on their purchases of branded and generic Revlimid.

515. The anticompetitive effects of Celgene's and BMS's unlawful monopolization continue to this day and will continue through at least January 2026.

516. As a direct result of Celgene's and BMS' unlawful monopolization, Plaintiffs have suffered and will continue to suffer injury to their business and property in the form of overcharges.

517. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

Jurisdiction	Relevant Statute(s)
Arizona	Ariz. Rev. Stat., § 44-1403, *et seq.*
Illinois	740 Ill. Comp. Stat. 10/1, *et seq.*
Iowa	Iowa Code § 553.1, *et seq.*
Kansas	Kan. Stat. Ann. § 50-101, *et seq.*
Michigan	Mich. Comp. Laws § 445.771, *et seq.*
Minnesota	Minn. Stat. §§ 325D.49, *et seq.*, and Minn. Stat. § 8.31, *et seq.*
Nevada	Nev. Rev. Stat. § 598A.010, *et seq.*
New Mexico	N.M. Stat. Ann. § 57-1-1, *et seq.*
North Carolina	N.C. Gen. Stat. § 75-1, *et seq.*
Oregon	Or. Rev. Stat. § 646.705, *et seq.*
Rhode Island	R.I. Gen. Laws § 6-36-1, *et seq.*
Utah	Utah Code Ann. §§ 76-10-3101, *et seq.*
West Virginia	W. Va. Code § 47-18-1, *et seq.*
Wisconsin	Wisc. Stat. § 133.01, *et seq.*

SEVENTH CLAIM FOR RELIEF
UNFAIR AND DECEPTIVE TRADE PRACTICES IN VIOLATION OF STATE LAW
(Against Defendants Celgene, BMS, and Natco/Teva)

518. Plaintiffs repeat and reallege every preceding allegation as if fully set forth herein.

519. Defendants Celgene, BMS, and Natco/Teva have engaged in unfair, unconscionable, deceptive, and fraudulent acts or practices and unfair methods of competition subject to and in violation of the following state unfair competition and consumer protection laws:

Jurisdiction	Relevant Statute(s)
Arizona	Ariz. Code § 44-1522, *et seq.*
Arkansas	Ark. Code Ann. § 4-88-101, *et seq.*
California	Cal. Bus. & Prof. Code §17200, *et seq.*
Colorado	Colo. Rev. Stat. § 6-1-101, *et seq.*
Florida	Fla. Stat. § 501.201, *et seq.*
Illinois	815 Ill. Comp. Stat. 505/1, *et seq.*
Kansas	Kan. Stat. Ann. § 50-623, *et seq.*
Massachusetts	Mass. Gen. Laws ch. 93A, *et seq.*
Michigan	Mich. Comp. Laws § 445.903, *et seq.*
Minnesota	Minn. Stat. §§ 325D.43-.48
Missouri	Mo. Rev. Stat. § 407.010, *et. seq.*
Montana	Mont. Code Ann. §§ 30-14-103, *et seq.*, and 30-14-201, *et seq.*
Nevada	Nev. Rev. Stat. § 598.0903, *et seq.*
New Jersey	N.J. Stat. § 56:8-1, *et seq.*, and § 56:8-107
New Mexico	N.M. Stat. Ann. § 57-12-1, *et seq.*
North Carolina	N.C. Gen. Stat. § 75-1.1, *et seq.*, and § 75-38
Oregon	Or. Rev. Stat. § 646.605, *et seq.*
Pennsylvania	73 Pa. Stat. Ann. § 201-1, *et seq.*

Utah	Utah Code Ann. § 13-11-1, *et seq.*
Virginia	Va. Code Ann. § 59.1-196, *et seq.*
West Virginia	W. Va. Code § 46A-6-101, *et seq.*
Wisconsin	Wisc. Stat. § 100.18, *et seq.*

520. Defendants' acts, omissions, misrepresentations, practices, and non-disclosures, as described herein, constitute a common and continuing course of conduct of unfair, unlawful, and/or fraudulent business acts or practices within the meaning of the above-identified state statutes and Section 1 of the Sherman Act.

521. Defendants' acts, omissions, misrepresentations, practices, and non-disclosures are unfair, unconscionable, unlawful, and/or fraudulent independently of whether they constitute a violation of the Sherman Act.

522. Defendants' acts or practices are fraudulent or deceptive within the meaning of the above-identified state statutes.

523. Defendants deceived Plaintiffs and others into purchasing branded and generic Revlimid at supracompetitive prices by, among other things, falsely representing that the pricing of Revlimid was the result of valid and enforceable patents, legitimate and justified patent litigation settlement agreements, and/or the result of competitive market forces, when the prices of Revlimid were actually the product of an anticompetitive agreement among Defendants Celgene, BMS, and Natco/Teva in restraint of trade.

524. Defendants' knowingly and purposely deceived Plaintiffs and others.

525. Defendants further took efforts to conceal their illegal agreements from Plaintiffs and others.

526. Defendants' willful, unconscionable and deceptive practices were and are an immediate cause of Plaintiffs' injury; specifically, Plaintiffs lacked any meaningful choice in purchasing branded and generic Revlimid because they were unaware of the overcharge, and there was no alternative source of supply through which Plaintiffs could avoid paying the overcharges. Defendants took grossly unfair advantage of Plaintiffs by knowingly and purposely deceiving Plaintiffs in a way that permitted Defendants to charge unconscionably higher prices for branded and generic Revlimid.

527. Defendants' conduct, including their illegal conspiracies to secretly fix and maintain the price of branded and generic Revlimid at supracompetitive levels and overcharge purchasers, was substantively unconscionable because it was one-sided and unfairly benefitted Defendants at the expense of Plaintiffs.

528. The aforementioned conduct resulted in a gross disparity between the value received by Plaintiffs and the prices paid by them for branded and generic Revlimid. Plaintiffs were not aware of Defendants' conspiracy and agreements to restrain trade and were therefore unaware that they were being unfairly and illegally overcharged.

EIGHTH CLAIM FOR RELIEF
UNFAIR AND DECEPTIVE TRADE PRACTICES IN VIOLATION OF STATE LAW
(Against Defendants Celgene, BMS, and Dr. Reddy's)

529. Plaintiffs repeat and reallege every preceding allegation as if fully set forth herein.

530. Defendants Celgene, BMS, and Dr. Reddy's have engaged in unfair, unconscionable, deceptive, and fraudulent acts or practices and unfair methods of competition subject to and in violation of the following state unfair competition and consumer protection laws:

Jurisdiction	**Relevant Statute(s)**
Arizona	Ariz. Code § 44-1522, *et seq.*
Arkansas	Ark. Code Ann. § 4-88-101, *et seq.*
California	Cal. Bus. & Prof. Code §17200, *et seq.*
Colorado	Colo. Rev. Stat. § 6-1-101, *et seq.*
Florida	Fla. Stat. § 501.201, *et seq.*
Illinois	815 Ill. Comp. Stat. 505/1, *et seq.*
Kansas	Kan. Stat. Ann. § 50-623, *et seq.*
Massachusetts	Mass. Gen. Laws ch. 93A, *et seq.*
Michigan	Mich. Comp. Laws § 445.903, *et seq.*
Minnesota	Minn. Stat. §§ 325D.43-.48
Missouri	Mo. Rev. Stat. § 407.010, *et. seq.*
Montana	Mont. Code Ann. §§ 30-14-103, *et seq.*, and 30-14-201, *et seq.*
Nevada	Nev. Rev. Stat. § 598.0903, *et seq.*
New Jersey	N.J. Stat. § 56:8-1, *et seq.*, and § 56:8-107
New Mexico	N.M. Stat. Ann. § 57-12-1, *et seq.*
North Carolina	N.C. Gen. Stat. § 75-1.1, *et seq.*, and § 75-38
Oregon	Or. Rev. Stat. § 646.605, *et seq.*
Pennsylvania	73 Pa. Stat. Ann. § 201-1, *et seq.*
Utah	Utah Code Ann. § 13-11-1, *et seq.*
Virginia	Va. Code Ann. § 59.1-196, *et seq.*

West Virginia	W. Va. Code § 46A-6-101, *et seq.*
Wisconsin	Wisc. Stat. § 100.18, *et seq.*

531. Defendants' acts, omissions, misrepresentations, practices, and non-disclosures, as described herein, constitute a common and continuing course of conduct of unfair, unlawful, and/or fraudulent business acts or practices within the meaning of the above-identified state statutes and Section 1 of the Sherman Act.

532. Defendants' acts, omissions, misrepresentations, practices, and non-disclosures are unfair, unconscionable, unlawful, and/or fraudulent independently of whether they constitute a violation of the Sherman Act.

533. Defendants' acts or practices are fraudulent or deceptive within the meaning of the above-identified state statutes.

534. Defendants deceived Plaintiffs and others into purchasing branded and generic Revlimid at supracompetitive prices by, among other things, falsely representing that the pricing of Revlimid was the result of valid and enforceable patents, legitimate and justified patent litigation settlement agreements, and/or the result of competitive market forces, when the prices of Revlimid were actually the product of an anticompetitive agreement among Defendants Celgene, BMS, and Dr. Reddy's in restraint of trade.

535. Defendants' knowingly and purposely deceived Plaintiffs and others.

536. Defendants' willful, unconscionable and deceptive practices were and are an immediate cause of Plaintiffs' injury; specifically, Plaintiffs lacked any meaningful choice in purchasing branded and generic Revlimid because they were unaware of the overcharge, and there was no alternative source of supply through which Plaintiffs could avoid paying the Revlimid overcharges. Defendants took grossly unfair advantage of Plaintiffs by knowingly and purposely deceiving Plaintiffs in a way that permitted Defendants to charge unconscionably higher prices for branded and generic Revlimid.

537. Defendants' conduct, including their illegal conspiracies to secretly fix and maintain the price of branded and generic Revlimid at supracompetitive levels and overcharge

purchasers, was substantively unconscionable because it was one-sided and unfairly benefitted Defendants at the expense of Plaintiffs.

538. The aforementioned conduct resulted in a gross disparity between the value received by Plaintiffs and the prices paid by them for branded and generic Revlimid. Plaintiffs were not aware of Defendants' conspiracy and agreements to restrain trade and were therefore unaware that they were being unfairly and illegally overcharged.

NINTH CLAIM FOR RELIEF
UNFAIR AND DECEPTIVE TRADE PRACTICES IN VIOLATION OF STATE LAW
(Against Defendants Celgene and BMS)

539. Plaintiffs repeat and reallege every preceding allegation as if fully set forth herein.

540. Defendants Celgene and BMS have engaged in unfair, unconscionable, deceptive, and fraudulent acts or practices and unfair methods of competition subject to and in violation of the following state unfair competition and consumer protection laws:

Jurisdiction	**Relevant Statute(s)**
Arkansas	Ark. Code Ann. § 4-88-101, *et seq.*
Arizona	Ariz. Code § 44-1522, *et seq.*
California	Cal. Bus. & Prof. Code §17200, *et seq.*
Colorado	Colo. Rev. Stat. § 6-1-101, *et seq.*
Florida	Fla. Stat. § 501.201, *et seq.*
Illinois	815 Ill. Comp. Stat. 505/1, *et seq.*
Indiana	Ind. Code § 24-5-0.5-1, *et seq.*
Kansas	Kan. Stat. Ann. § 50-623, *et seq.*
Massachusetts	Mass. Gen. Laws ch. 93A, *et seq.*
Michigan	Mich. Comp. Laws § 445.903, *et seq.*
Minnesota	Minn. Stat. §§ 325D.43-.48
Missouri	Mo. Rev. Stat. § 407.010, *et. seq.*
Montana	Mont. Code Ann. §§ 30-14-103, *et seq.*, and 30-14-201, *et seq.*
Nevada	Nev. Rev. Stat. § 598.0903, *et seq.*
New Jersey	N.J. Stat. § 56:8-1, *et seq.*, and § 56:8-107
New Mexico	N.M. Stat. Ann. § 57-12-1, *et seq.*
North Carolina	N.C. Gen. Stat. § 75-1.1, *et seq.*, and § 75-38
Oregon	Or. Rev. Stat. § 646.605, *et seq.*
Pennsylvania	73 Pa. Stat. Ann. § 201-1, *et seq.*
Utah	Utah Code Ann. § 13-11-1, *et seq.*
Virginia	Va. Code Ann. § 59.1-196, *et seq.*
West Virginia	W. Va. Code § 46A-6-101, *et seq.*
Wisconsin	Wisc. Stat. § 100.18, *et seq.*

541. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Plaintiffs were deprived of the opportunity and ability to purchase generic Revlimid at competitive prices and, instead, were forced to pay supracompetitive prices for both branded and generic Revlimid.

542. Defendants' acts, omissions, misrepresentations, practices, and non-disclosures, as described herein, constitute a common and continuing course of conduct of unfair, unlawful, and/or fraudulent business acts or practices within the meaning of the above-identified state statutes and Section 2 of the Sherman Act.

543. Defendants' acts, omissions, misrepresentations, practices, and non-disclosures are unfair, unconscionable, unlawful, and/or fraudulent independently of whether they constitute a violation of the Sherman Act.

544. Defendants' acts or practices are fraudulent or deceptive within the meaning of the above-identified state statutes.

545. Defendants deceived Plaintiffs and others into purchasing branded and generic Revlimid at supracompetitive prices by falsely representing, among other things, that Celgene and BMS had valid patents for Revlimid and by hiding the anticompetitive terms of Celgene's and BMS's patent litigation settlement agreements with generic manufacturers. In particular, Defendants have concealed illegal agreements with, at a minimum, Natco/Teva and Dr. Reddy's, to restrain the amount of generic Revlimid for trade in the market from March 2022 until at least January 2026.

546. Defendants knowingly and purposely deceived Plaintiffs and others.

547. Defendants' willful, unconscionable and deceptive practices were and are an immediate cause of Plaintiffs' injury; specifically, Plaintiffs were forced to pay supracompetitive prices for both branded and generic Revlimid due to the illegal agreements between Defendants because Plaintiffs were unaware of the invalidity of Defendants' patents and the illegal agreements between Defendants and there was no alternative source of supply through which Plaintiffs could avoid paying the Revlimid overcharges. Defendants took grossly unfair advantage

of Plaintiffs by knowingly and purposely deceiving Plaintiffs in a way that permitted Defendants to charge unconscionably higher prices for branded and generic Revlimid.

548. Defendants' conduct, including their illegal conspiracies to secretly fix and maintain the price of branded and generic Revlimid at supracompetitive levels and overcharge purchasers, was substantively unconscionable because it was one-sided and unfairly benefitted Defendants at the expense of Plaintiffs.

549. The aforementioned conduct resulted in a gross disparity between the value received by Plaintiffs and the prices paid by them for branded and generic Revlimid. Plaintiffs were not aware of Defendants' conspiracy and agreements to restrain trade and were therefore unaware that they were being unfairly and illegally overcharged.

TENTH CLAIM FOR RELIEF
UNJUST ENRICHMENT
(Against All Defendants)

550. Plaintiffs repeat and reallege every preceding allegation as if fully set forth herein.

551. This claim is pleaded in the alternative to the other claims in this Complaint and brought under the equity precedents of the states of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Florida, Illinois, Indiana, Iowa, Kansas, Kentucky, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nevada, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin

552. From at least 2019 and moving forward until at least January 2026, Defendants have unlawfully benefited and will continue to unlawfully benefit from their sales of branded and generic Revlimid because of the unlawful and inequitable acts alleged in this Complaint. Defendants unlawfully overcharged Plaintiffs, who purchased branded and generic Revlimid at prices that were more than they would have been but for Defendants' unlawful actions. Plaintiffs are intended purchasers of branded and generic Revlimid.

553. Defendants' financial benefits resulting from their unlawful and inequitable acts are traceable to overpayments by Plaintiffs.

554. Plaintiffs have conferred upon Defendants an economic benefit, in the nature of profits resulting from unlawful overcharges for branded and generic Revlimid, to the economic detriment of Plaintiffs.

555. Defendants have been enriched by revenue resulting from unlawful overcharges for branded and generic Revlimid while Plaintiffs have been impoverished by the overcharges they paid for branded and generic Revlimid, which were imposed solely through Defendants' unlawful conduct. Defendants' enrichment and Plaintiffs' impoverishment are connected.

556. There is no justification for Defendants' retention of, and enrichment from, the benefits they received, which caused impoverishment to Plaintiffs, because Plaintiffs paid supracompetitive prices that inured to Defendants' benefit, and it would be inequitable for Defendants to retain any revenue gained from their unlawful overcharges. Plaintiffs did not interfere with Defendants' affairs in any manner that conferred these benefits upon Defendants.

557. The benefits conferred upon Defendants were not gratuitous, in that they constituted revenue created by unlawful overcharges arising from Defendants' illegal and unfair actions to artificially inflate and maintain the price of branded and generic Revlimid.

558. The benefits conferred upon Defendants are measurable, in that the revenue Defendants have earned due to their unlawful overcharges for branded and generic Revlimid are ascertainable by review of sales records.

559. Defendants have paid no consideration to any other person for any of the unlawful benefits they received from Plaintiffs with respect to Defendants' sales of branded and generic Revlimid.

560. The economic benefit of overcharges and monopoly profits derived by Defendants through charging supracompetitive and artificially inflated prices for branded and generic Revlimid is a direct and proximate result of Defendants' unlawful practices.

561. The financial benefits derived by Defendants rightfully belong to Plaintiffs because Plaintiffs paid supracompetitive prices for branded and generic Revlimid since at least 2019, which inured to the benefit of Defendants.

562. It would be inequitable under unjust enrichment principles under the law of states of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Florida, Illinois, Indiana, Iowa, Kansas, Kentucky, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nevada, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin, for Defendants to be permitted to retain any of the overcharges for branded and generic Revlimid derived from Defendants' unlawful, unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

563. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiffs. Defendants consciously accepted the benefits and continue to do so as of the date of this filing, as prices for branded and generic Revlimid remain artificially inflated and will continue to do so until at least January 2026.

564. Defendants should be compelled to disgorge in a common fund for the benefit of Plaintiffs all unlawful or inequitable proceeds they received from their sales of branded and generic Revlimid since at least 2019.

565. A constructive trust should be imposed upon all unlawful or inequitable sums received by Defendants traceable to indirect purchases of branded and generic Revlimid by Plaintiffs. Plaintiffs have no adequate remedy at law.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rules of Civil Procedure 38(b), Plaintiffs hereby demand a trial by jury of all issues triable to a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

a. A declaration that the conduct alleged above is in violation of: (i) Sections 1 of the Sherman Act, 15 U.S.C. § 1; (ii) Section 2 of the Sherman Act, 15 U.S.C. § 2; and (iii) all applicable state antitrust, unfair competition and consumer protection laws set forth herein;

b. Plaintiffs recover damages, to the maximum extent allowed by state and federal laws, and that a judgement in favor of Plaintiff be entered against Defendants jointly and severally, as appropriate, in an amount to be trebled to the extent permitted by law;

c. Plaintiffs recover damages and/or restitution, to the maximum extent allowed by such laws, including disgorgement of profits Defendants obtained as a result of their acts of unfair competition and acts of unjust enrichment;

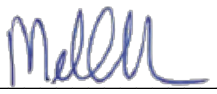
d. Defendants and their affiliates, assignees, subsidiaries, successors, and transferrers, as well as their officers, directors, partners, agents, employees, and all other persons acting or claiming to act on their behalf or in concert with them, be permanently enjoined from engaging in any anticompetitive conduct or from adopting in the future any practice, plan, program, scheme, or device having a similar purpose or effect to the anticompetitive actions set forth above;

e. Plaintiffs recover their costs of suit, including reasonable attorneys' fees, a provided by law; and

f. Plaintiffs have such other and further relief as the Court may deem just an appropriate.

Dated: October 6, 2023

Respectfully submitted,



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